

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 229. Food and Drug

Subchapter J. Minimum Standards For Narcotic Treatment Programs

Amendment §229.145

Subchapter L. Licensure Of Food Manufacturers, Food Wholesalers, and Warehouse Operators

Amendment §229.182

Subchapter U. Permitting Retail Food Establishments

Amendment §229.372

Subchapter X. Licensing of Device Distributors and Manufacturers

Amendment §229.439

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §229.145 concerning the Narcotic Treatment Program fees, §229.182 concerning Food Manufacturers, Food Wholesalers, and Warehouse Operators fees, §229.372 concerning Permitting of Retail Food Establishments fees, and §229.439 concerning the Device Distributors and Device Manufacturers fees.

BACKGROUND AND PURPOSE

The Texas Legislature passed the General Appropriations Act, Senate Bill 1, 79th Legislature, Regular Session (2005). Article II, Rider 85 makes a portion of the appropriation contingent upon collection of fees above the Comptroller of Public Accounts' Biennial Revenue estimate. To meet these requirements, a cost recovery fee is included in this amendment.

Programs with regulatory authority over narcotic treatment, food manufacturers, food wholesalers, warehouse operators, retail food establishments, and device distributors and manufacturers, were evaluated to determine the level of increase in fees based on the following criteria: The date of the last fee increase for the specific program area; licensee's ability to pay in comparison to average salary of professionals; the percentage of revenue above costs for the specific program; the cost of licenses compared to other similar licenses; and the value added analysis of the license. Additional costs of administration and enforcement of the program, due to a recent legislative increase in pay, longevity pay, and travel reimbursement, were also factored in to determine the direct and indirect costs of each program.

SECTION-BY-SECTION SUMMARY

Amendments to §229.145 contain increases in fees for permits, patient certificates, renewal certificates and delinquency charges for renewing expired permits or submission of late status reports, for narcotic treatment licensees. References to one-year permits have been deleted because the program no longer issues one-year permits. Specifically, §229.145 increases the fees by 40%, including a \$300 increase in the initial application fee stated in §229.145(b)(1); §229.145(b)(2) increases the initial patient fee by \$50 and increases the patient fee certificate by \$20; §229.145(b)(4)(A) increases the delinquency fee for an expired patient certificate by \$2; §229.145(b)(4)(B) increases a delinquency fee for submission of a status report after expiration of a patient certificate by \$100; §229.145(b)(4)(C) increases the renewal fee of a patient certificate by \$20; and §229.145(b)(4)(D) increases the fee for each additional patient requiring a certificate by \$20.

Amendments to §229.182(a)(7) change the department name from "Texas Department of Health or its successor" to "Department of State Health Services" to state the new department name. Amendments to §229.182 contain increases in licensing fees for food manufacturers, food wholesalers, and wholesalers with combination products for initial and renewal applications per location, based upon gross annual sales. References to one-year permits have been deleted because the program no longer issues one-year permits. Specifically, new §229.182(b)(1)(A) increases the license fee for food manufacturers with gross annual sales of \$0.00 - \$9,999.99 by \$50; new §229.182(b)(1)(B) increases the license fee for food manufacturers with gross annual sales of \$10,000.00 - \$24,999.99 by \$50; new §229.182(b)(1)(C) increases the license fee for food manufacturers with gross annual sales of \$25,000.00 - \$99,999.99 by \$50; new §229.182(b)(1)(D) increases the license fee for food manufacturers with gross annual sales of \$100,000.00 - \$199,999.99 by \$60; new §229.182(b)(1)(E) increases the license fee for food manufacturers with gross annual sales of \$200,000.00 - \$999,999.99 by \$100; new §229.182(b)(1)(F) increases the license fee for food manufacturers with gross annual sales of \$1 million - \$9,999,999.99 by \$120; new §229.182(b)(1)(G) increases the license fee for food manufacturers with gross annual sales of greater than or equal to \$10 million by \$180; new §229.182(b)(2)(A) increases the license fee for food wholesalers with gross annual sales of \$0.00 - \$199,999.99 by \$50; new §229.182(b)(2)(B) increases the license fee for food wholesalers with gross annual sales of \$200,000.00 - \$499,999.99 by \$50; new §229.182(b)(2)(C) increases the license fee for food wholesalers with gross annual sales of \$500,000.00 - \$999,999.99 by \$80; new §229.182(b)(2)(D) increases the license fee for food wholesalers with gross annual sales of \$1 million - \$9,999,999.99 by \$100; and new §229.182(b)(2)(E) increases the license fee for food wholesalers with gross annual sales of greater than or equal to \$10 million by \$150.

Amendments to §229.372 contain increases in retail food establishment permit fees based on gross annual volume of food sales or establishment type. References to one-year permits have been deleted because the program no longer issues one-year permits. Specifically, §229.372(a)(1)(A) increases the fee for an establishment with a gross annual volume of food sales of \$0 - \$49,999.99 by 25% or \$50; §229.372(a)(1)(B) increases the fee for an establishment with a gross annual volume of sales of \$50,000 - \$149,999.99 by 25% or \$100; §229.372(a)(1)(C) increases the fee for an establishment with a gross annual volume of sales of \$150,000 or more by 17% or \$100; §229.372(a)(2) increases the fee for a for-profit school contractor by 25% or \$50; §229.372(a)(3)(B) increases the fee for mobile food unit by 25% or \$50; §229.372(a)(4) increases the fee for a roadside food vendor by 25% or \$50; and §229.372(a)(5) increases the fee for a child care center by 25% or \$50.

Amendments to §229.439 contain increases in fees for licenses and renewal licenses for device distributors or manufacturers. References to one-year permits have been deleted because the program no longer issues one-year permits. Specifically, §229.439 increases the fees by 20%, §229.439(a)(1)(A) increases the license fee for distributors with gross annual sales of \$0 - \$499,999.99 by \$80; §229.439(a)(1)(B) increases the license fee for distributors with gross annual sales of \$500,000 - \$9,999,999.99 by \$180; §229.439(a)(1)(C) increases the license fee for distributors with gross annual sales greater than or equal to \$10 million by \$280; §229.439(a)(3)(A) increases the license fee for manufacturers with gross annual sales of \$0 - \$499,999.99 by \$80; §229.439(a)(3)(B) increases the license fee for manufacturers with gross annual sales of \$500,000 - \$9,999,999.99 by \$360; and §229.439(a)(3)(C) increases the license fee for manufacturers with gross annual sales of greater than or equal to \$10 million by \$600.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each fiscal year of the first five years §229.145, §229.182, §229.372, and §229.439 are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed.

The effect of §229.145 on state government will be an increase in revenue to the state of \$72,033 in 2006 and \$108,050 in 2007 through 2010.

The effect of §229.182 on state government will be an increase in revenue to the state of \$427,973 in 2006 and \$641,960 in 2007 through 2010.

The effect of §229.372 on state government will be an increase in revenue to the state of \$195,333 in 2006 and \$293,000 in 2007 through 2010.

The effect of §229.439 on state government will be an increase in revenue to the state of \$34,147 in 2006 and \$51,220 in 2007 through 2010.

These additional revenues will offset the increased costs associated with the legislative increase in pay, longevity pay, and travel reimbursement. Implementation of the proposed sections will not result in any fiscal implications for local governments.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated economic costs to small businesses or micro-businesses required to comply with §229.145, §229.182, §229.372, and §229.439 as proposed.

There will be an increase of 40% in the §229.145 licensing fees for businesses or persons operating a narcotic treatment program. The probable economic cost to persons required to comply with the section as proposed will be an increase in permit fees from between \$2 - \$300 for the two-year term of the license.

There will be an increase in the §229.182 licensing fees for businesses or persons required to maintain a food manufacturer license, food wholesaler license or wholesaler with combination license. The probable economic cost to persons required to comply with the §229.182 fee for the license will increase from \$50-\$180 for the two-year term of the license.

There will be an increase in the §229.372 licensing fees for businesses or persons required to maintain a retail food establishment license. The probable economic cost to persons required to comply with the §229.372 fee for the license will increase 25% or \$50 every two years if food sales are less than \$50,000, 25% or \$100 every two years if food sales are \$50,000 to \$150,000, or 17% or \$100 every two years if food sales are \$150,000 or more. Specific types of retail food establishments with flat rate fees will increase 25% or \$50 for the two-year term of the license.

There will be an increase of 20% in the §229.439 licensing fees for businesses or persons operating as device distributors and manufacturers. The probable economic cost to persons required to comply with the section as proposed will be an increase in license fees from \$80 - \$600 for the two-year term of the license.

There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of §229.145, §229.182, §229.372, and §229.439.

The public benefit anticipated as a result of enforcing or administering §229.145 is to generate funding to operate the program to continue enforcement of the minimum standards for narcotic treatment programs to ensure the safety of patients enrolled in these substance abuse programs and the general public.

The public benefit anticipated as a result of enforcing or administering §229.182 is to generate funding to operate the program to ensure the safety of foods manufactured, stored and distributed to the public.

The public benefit anticipated as a result of enforcing or administering §229.372 is to generate funding to operate the program that conducts inspections of retail food establishments to ensure the reduction of the potential for food borne illness to the public and Texas consumers.

The public benefit anticipated as a result of enforcing or administering §229.439 is to generate funding to operate the program to continue enforcement of the minimum standards for device distributors and manufacturers, ensuring these medical products are safe and effective for use by the public and consumers.

REGULATORY ANALYSIS

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

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal concerning §229.145 and §229.439 may be submitted to Tom Brinck, Policy/Standards/Quality Assurance Unit, Environmental and Consumer Safety Section, Division of Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756,

(512) 834-6755, ext. 2388 or by email to Tom.Brinck@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the Texas Register.

Comments on the proposal concerning §229.372 may be submitted to John D. Lattimore, Food Establishment Group, Policy/Standards/Quality Assurance Unit, Environmental and Consumer Safety Section, Division of Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6753, ext. 2023 or by email to John.Lattimore@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the Texas Register.

Comments on the proposal regarding §229.182 may be submitted to Julie Loera, Policy/Standards/Quality Assurance Unit, Environmental and Consumer Safety Section, Division of Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6670, ext. 2145 or by email to Julie.Loera@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the Texas Register.

STATUTORY AUTHORITY

The proposed amendments to §§229.145, 229.182, 229.372, and 229.439, are authorized by Health and Safety Code §§145.010, 146.005, 431.204, 431.222, 431.276, 432.009, 437.0125, 438.047, 438.106, 441.001, 441.003, and 466.023, which require the department to charge fees for issuing or renewing a license or permit; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Chapter 1001, Health and Safety Code.

The proposed amendments affect the Health and Safety Code, Chapters 145, 146, 431, 432, 437, 438, 441, and 466 and 1001; and Government Code, Chapter 531.

LEGAL CERTIFICATION

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

Legend: (Proposed Amendments)

Single Underline = Proposed new language

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

Regular Print = Current language

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

§229.145. Applications, Fees, Permits.

(a) (No change.)

(b) Fees and fee assessments.

(1) Initial fees. All applicants for an NTP permit must submit an initial application fee of \$1,000 **[\$700]** with each application. All initial fees are nonrefundable. An application will not be processed unless it is submitted with the initial fees.

(2) Patient fees. A permit holder must submit a patient fee for each patient the NTP is approved to treat. The patient fee must be paid no later than 30 days from the date the permit is issued. A nonrefundable initial fee of \$150 **[\$100]** must be submitted for each medication unit requested in the initial application. The NTP or medication unit will be issued a patient fee certificate for a **[one or]** two-year term[, **as determined by the department**]. The patient fee is \$60 per patient. **[fees are as follows:]**

[(A) \$20 for each patient for a one-year patient fee certificate; or]

[(B) \$40 for each patient for a two-year patient fee certificate.]

(3) (No change.)

(4) Renewal permit fees. A permit holder must submit a renewal application form, a current status report, and renewal fees prior to the expiration date of the current patient fee certificate. A renewal permit shall only be issued when all past due fees and delinquency fees are paid.

(A) A permit holder who submits a renewal application and fees after the expiration date must pay delinquency fees of \$5 **[\$3]** for each patient the NTP is approved to treat.

(B) A permit holder who submits a current status report after the expiration date must pay a delinquency fee of \$350 **[\$250]**.

(C) Renewal patient fee certificates are issued for **[one or]** two-year terms **[as determined by the department]**. The renewal fee is nonrefundable and is \$60 per patient. **[Renewal fees are nonrefundable and are as follows:]**

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or] [(i) \$20 for each patient for a one-year patient fee certificate;

[(ii) \$40 for each patient for a two-year patient fee certificate.]

(D) Increase in patient certificates. A permit holder who requests an increase in the number of patients the NTP is approved to treat prior to the expiration of a current patient certificate must provide documentation demonstrating adequate facility and staff capacity to accommodate an increase. Temporary transfer patients should not be included. The patient fee is \$60 for each additional patient. **[Patient fees for each additional patient should be submitted based on the permit holders current permit term as follows:]**

or] [(i) \$20 for each additional patient for a one-year certificate;

[(ii) \$40 for each additional patient for a two-year certificate.]

(c) – (d) (No change.)

§229.182. Licensing/Registration Fee and Procedures.

(a) License/registration required.

(1) -(6) (No change.)

(7) A retail food store that also manufactures food and is required to be permitted by the Department of State Health Services **[Texas Department of Health or its successor]** (department) pursuant to Health and Safety Code, Chapter 437, and the Texas Food Establishment Regulations, §229.370 and §229.371 of this title (relating to Permitting Retail Food Establishments), will be issued only one license or permit. The license or permit fee to be paid will be the higher of the two applicable fees.

(8) - (9) (No change.)

(b) Licensing and registration fees.

[(1) Food manufacturer. This subsection applies to all new and renewal applications received by the department prior to January 1, 2005. Licenses issued under this subsection expire one year from the start date of the regulated activity. All food manufacturers in Texas shall obtain a license annually with the department and shall pay a license fee as follows:]

[(A) \$25 for each place of business having gross annual manufactured food sales of \$0.00 - \$9,999.99;]

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[(B) \$50 for each place of business having gross annual manufactured food sales of \$10,000 - \$24,999.99;]

[(C) \$100 for each place of business having gross annual manufactured food sales of \$25,000 - \$99,999.99;]

[(D) \$250 for each place of business having gross annual manufactured food sales of \$100,000 - \$199,999.99;]

[(E) \$400 for each place of business having gross annual manufactured food sales of \$200,000 - \$999,999.99;]

[(F) \$500 for each place of business having gross annual manufactured food sales of \$1 million - \$9,999,999.99; and]

[(G) \$750 for each place of business having gross annual manufactured food sales greater than or equal to \$10 million.]

(1) [(2)] Food manufacturer. No person may operate or conduct business as a food manufacturer in this state without first obtaining a license from the department. [This subsection applies to all new and renewal applications received by the department on or after January 1, 2005.] Licenses issued under this subsection expire two years from the start date of the regulated activity. All applicants for a new or renewal food manufacturer's license [food manufacturers in Texas shall obtain a license every two years with the department and] shall pay a license fee as follows:

(A) \$100 [**\$50**] for each place of business having gross annual manufactured food sales of \$0.00 - \$9,999.99;

(B) \$150 [**\$100**] for each place of business having gross annual manufactured food sales of \$10,000 - \$24,999.99;

(C) \$250 [**\$200**] for each place of business having gross annual manufactured food sales of \$25,000 - \$99,999.99;

(D) \$560 [**\$500**] for each place of business having gross annual manufactured food sales of \$100,000 - \$199,999.99;

(E) \$900 [**\$800**] for each place of business having gross annual manufactured food sales of \$200,000 - \$999,999.99;

(F) \$1120 [**\$1000**] for each place of business having gross annual manufactured food sales of \$1 million - \$9,999,999.99; and

(G) \$1680 [**\$1500**] for each place of business having gross annual manufactured food sales greater than or equal to \$10 million.

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[(3) Food wholesaler. This subsection applies to all new and renewal applications received by the department prior to January 1, 2005. Licenses issued under this subsection expire one year from the start date of the regulated activity. All food wholesalers in Texas shall obtain a license annually with the department. Except as provided for in paragraph (5) of this subsection, food wholesalers shall pay a license fee as follows:]

[(A) \$100 for each place of business having gross annual food sales of \$0.00 - \$199,999.99;]

[(B) \$200 for each place of business having gross annual food sales of \$200,000 - \$499,999.99;]

[(C) \$300 for each place of business having gross annual food sales of \$500,000 - \$999,999.99;]

[(D) \$400 for each place of business having gross annual food sales of \$1 million - \$9,999,999.99; and]

[(E) \$600 for each place of business having gross annual food sales of greater than or equal to \$10 million.]

(2) [(4) Food wholesaler. No person may operate or conduct business as a food wholesaler in this state without first obtaining a food wholesaler's license from the department. [This subsection applies to all new and renewal applications received by the department on or after January 1, 2005.] Licenses issued under this subsection expire two years from the start date of the regulated activity. Except as provided for in paragraph (4) [(7)] of this subsection, all food wholesalers [in Texas shall obtain a license every two years with the department and] shall pay a license fee as follows:

(A) \$250 [\$200**] for each place of business having gross annual food sales of \$0.00 - \$199,999.99;**

(B) \$450 [\$400**] for each place of business having gross annual food sales of \$200,000 - \$499,999.99;**

(C) \$680 [\$600**] for each place of business having gross annual food sales of \$500,000 - \$999,999.99;**

(D) \$900 [\$800**] for each place of business having gross annual food sales of \$1 million - \$9,999,999.99; and**

(E) \$1350 [\$1200**] for each place of business having gross annual food sales of greater than or equal to \$10 million.**

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[(5) Wholesaler with combination products. This subsection applies to all new and renewal applications received by the department prior to January 1, 2005. Licenses issued under this subsection expire one year from the start date of the regulated activity. A food wholesaler who is required to be licensed under this section and who is also required to be licensed as a wholesale distributor of drugs under §229.252(a)(1) of this title (relating to Licensing Fee and Procedures) and/or as a device distributor under §229.439(a)(1) of this title (relating to Licensure Fees) shall pay a combined licensure fee for each place of business. The licensure fee shall be based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices) as follows:]

[(A) \$200 for each place of business having combined gross annual sales of \$0.00 - \$199,999.99;]

[(B) \$300 for each place of business having combined gross annual sales of \$200,000 - \$499,999.99;]

[(C) \$400 for each place of business having combined gross annual sales of \$500,000 - \$999,999.99;]

[(D) \$500 for each place of business having combined gross annual sales of \$1 million - \$9,999,999.99; and]

[(E) \$750 for each place of business having combined gross annual sales greater than or equal to \$10 million.]

(3) [(6)] Wholesaler with combination products. [This subsection applies to all new and renewal applications received by the department on or after January 1, 2005. Licenses issued under this subsection expire two years from the start date of the regulated activity.] A person who is required to be licensed as a food wholesaler **[who is required to be licensed] under this section and who is also required to be licensed as a wholesale distributor of drugs under §229.252(a)(1) of this title or as a device distributor under §229.439(a)(1) of this title shall pay a combined licensure fee for each place of business. The licensure fee shall be based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices) as follows:**

(A) \$400 for each place of business having combined gross annual sales of \$0.00 - \$199,999.99;

(B) \$600 for each place of business having combined gross annual sales of \$200,000 - \$499,999.99;

(C) \$800 for each place of business having combined gross annual sales of \$500,000 - \$999,999.99;

(D) \$1000 for each place of business having combined gross annual sales of \$1 million - \$9,999,999.99; and

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(E) \$1500 for each place of business having combined gross annual sales greater than or equal to \$10 million.

(4) ~~[(7)]~~ Food wholesaler registration. Except as provided in paragraph (3) [paragraphs (5) and (6)] of this subsection, a food wholesaler is not required to obtain a license under this section for a place of business if all of the food distributed from that place of business will be stored in a warehouse licensed under this section. A food wholesaler that is not required to obtain a license for a place of business under this section shall register each place of business with the department pursuant to subsection (d)(2) of this section, but only one registration fee must be paid by each such food wholesaler. A food wholesaler who meets this subsection's requirements shall pay a registration fee of \$100. A registration issued under this subsection expires two years from the start date of the regulated activity. [as follows:]

[(A) \$50 for a one year registration, on a form received by the department prior to January 1, 2005. A registration issued under this subsection expires one year from the start date of the regulated activity;]

[(B) \$100 for a two-year registration, on a form received by the department on or after January 1, 2005. A registration issued under this subsection expires two years from the start date of the regulated activity;]

[(8) Warehouse operator. This subsection applies to all new and renewal applications received by the department prior to January 1, 2005. Licenses issued under this subsection expire one year from the start date of the regulated activity. All warehouse operators in Texas shall obtain a license annually with the department. The fee paid must be based on the maximum amount of square feet dedicated to food storage during the licensing period. A warehouse operator shall pay a license fee as follows:]

[(A) \$175 for each place of business having food storage of 0 - 6,000 square feet;]

[(B) \$350 for each place of business having food storage of 6,001 - 24,000 square feet;]

[(C) \$525 for each place of business having food storage of 24,001 - 75,000 square feet;]

[(D) \$700 for each place of business having food storage of 75,001 - 250,000 square feet; and]

[(E) \$1000 for each place of business having food storage of 250,001 or more square feet.]

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(5) [(9)] Warehouse operator. No person may operate or conduct business as a warehouse operator in this state without first obtaining a license from the department. [This subsection applies to all new and renewal applications received by the department on or after January 1, 2005.] Licenses issued under this subsection expire two years from the start date of the regulated activity. **[All warehouse operators in Texas shall obtain a license every two years with the department.]** License fees are [The fee paid must be] based on the maximum amount of square feet dedicated to food storage during the licensing period. A warehouse operator shall pay a license fee as follows:

(A) \$350 for each place of business having food storage of 0 - 6,000 square feet;

(B) \$700 for each place of business having food storage of 6,001 - 24,000 square feet;

(C) \$1,050 for each place of business having food storage of 24,001 - 75,000 square feet;

(D) \$1,400 for each place of business having food storage of 75,001 - 250,000 square feet; and

(E) \$2,000 for each place of business having food storage of 250,001 or more square feet.

(6) [(10)] A firm that has more than one business location may request a one-time proration of fees when applying for a license for each new location. Upon approval by the department, the expiration date of the license for the new location will be established the same as the firm's previously licensed locations.

(7) [(11)] For all applications and renewal applications, the department is authorized to collect subscription and convenience fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.

(8) [(12)] All license/registration fees paid under this section are non-refundable.

(9) [(13)] If the license/registration category changes during the license period, the license shall be renewed in the proper category at the time of renewal.

(c) – (e) (No change)

(f) Issuance of license/registration. The [As applicable, the] department may license/register a manufacturer, food wholesaler, or warehouse operator who meets the requirements of this section and §229.183 of this title (relating to Minimum Standards for Licensure/Registration).

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(1) The initial license/registration shall be valid for **[one year from the start date of the regulated activity which becomes the anniversary date, for all applications received by the department prior to January 1, 2005, and for]** two years from the **[anniversary]** date the license/registration was issued **[for all applications received on or after January 1, 2005]**.

(2) The renewal license/registration shall be valid for **[one year from the anniversary date, unless an amendment occurs, for all applications received by the department prior to January 1, 2005, and for]** two years from the **[anniversary]** date the license/registration was issued **[for all applications received on or after January 1, 2005]**.

(3) (No change.)

(g) – (i) (No Change)

§229.372. Permitting Fees and Procedures.

(a) Permitting fees.

(1) A person who operates a food establishment shall obtain a permit from the department and pay a permit fee for each establishment unless specifically exempted under subsection (b) or (c) of this section. All permit fees are nonrefundable. Permits are issued for a **[one or]** two-year term **[as determined by the department]**. The fees are based on gross annual volume of sales as follows:

(A) for an establishment with gross annual volume of food sales of \$0 - \$49,999.99, the fee is \$250; **[:]**

[(i) \$100 for a one-year permit; or]

[(ii) \$200 for a two-year permit.]

(B) for an establishment with gross annual volume of food sales of \$50,000 - \$149,999.99, the fee is \$500; **[:]**

[(i) \$200 for a one-year permit; or]

[(ii) \$400 for a two-year permit.]

(C) for an establishment with gross annual volume of food sales of \$150,000 or more, the fee is \$750. **[:]**

[(i) \$325 for a one-year permit; or]

[(ii) \$650 for a two-year permit.]

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(2) A person who contracts with a school to provide food services on a for-profit basis shall obtain a permit and pay a permit fee for each school where food services are provided. Permits are issued for a **[one or]** two-year term **[as determined by the department]**. The permit fee is \$250. **[fees are as follows:]**

[(A) \$100 for a one-year permit; or]

[(B) \$200 for a two-year permit.]

(3) A person who operates a mobile food unit shall obtain a permit from the department for each mobile food unit operated.

(A) (No change.)

(B) Permits are issued for a **[one or]** two-year term **[as determined by the department]**. The permit fee is \$250. **[Permit fees are as follows:]**

[(i) \$100 for a one-year permit; or]

[(ii) \$200 for a two-year permit.]

(4) Each roadside food vendor shall obtain a permit and pay a fee. All fees are nonrefundable. A permit will be issued for a **[one or]** two-year term **[as determined by the department]**. The permit fee is \$250. **[fees are as follows:]**

[(A) \$100 for a one-year permit; or]

[(B) \$200 for a two-year permit.]

(5) Each child care center providing food services shall obtain a permit and pay a fee. All fees are nonrefundable. A permit will be issued for a **[one or]** two-year term **[, as determined by the department]**. The permit fee is \$250. **[fees are as follows:]**

[(A) \$100 for a one-year permit; or]

[(B) \$200 for a two-year permit.]

(6) – (8) (No change.)

(b) – (l) (No change.)

§229.439. Licensure Fees.

(a) License fee.

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(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 **[one or]** two-year terms **[as determined by the department]**. 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 as follows:

(A) for [For] a distributor with gross annual device sales of \$0 - \$499,999.99, the fee is \$480; [:]

[(i) \$200 for a one-year license; or]

[(ii) \$400 for a two-year license.]

(B) for [For] a distributor with gross annual device sales of \$500,000 - \$9,999,999.99, the fee is \$1,080; or [:]

[(i) \$450 for a one-year license; or]

[(ii) \$900 for a two-year license.]

(C) for [For] a distributor with gross annual device sales greater than or equal to \$10 million, the fee is \$1,680. [:]

[(i) \$700 for a one-year license; or]

[(ii) \$1,400 for a two-year license.]

(2) A person who is required to be licensed as a device distributor [who is required to be licensed] 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 **[one or]** two-year terms **[as determined by the department]**. The licensing fee is based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices) as follows:

(A) for [For] each place of business having combined gross annual sales of \$0 - \$199,999.99, the fee is \$400; [;]

[(i) \$200 for a one-year license; or]

[(ii) \$400 for a two-year license.]

(B) for [For] each place of business having combined gross annual sales of \$200,000 - \$499,999.99, the fee is \$600; [;]

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[(i) \$300 for a one-year license; or]

[(ii) \$600 for a two-year license.]

(C) for [For] each place of business having combined gross annual sales of \$500,000 - \$999,999.99, the fee is \$800; [;]

[(i) \$400 for a one-year license; or]

[(ii) \$800 for a two-year license.]

(D) for [For] each place of business having combined gross annual sales of \$1 million - \$9,999,999.99, the fee is \$1,000; or [;]

[(i) \$500 for a one-year license; or]

[(ii) \$1,000 for a two-year license.]

(E) for [For] each place of business having combined gross annual sales greater than or equal to \$10 million, the fee is \$1,500. [;]

[(i) \$750 for a one-year license; or]

[(ii) \$1,500 for a two-year license.]

(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 **[one or]** two-year terms **[as determined by the department]**. License fees are based on the gross annual device sales as follows:

(A) for [For] a manufacturer with gross annual device sales of \$0 - \$499,999.99, the fee is \$480; [;]

[(i) \$200 for a one-year license; or]

[(ii) \$400 for a two-year license.]

(B) for [For] a manufacturer with gross annual device sales of \$500,000 - \$9,999,999.99, the fee is \$2,160; or [;]

[(i) \$900 for a one-year license; or]

[(ii) \$1,800 for a two-year license; and]

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(C) ~~for~~ **[For]** a manufacturer with gross annual device sales greater than or equal to \$10 million, ~~the fee is \$3,600.~~ **[;]**

[(i) \$1,500 for a one-year license; or]

[(ii) \$3,000 for a two-year license.]

(b) - (d) (No change.)