

## **TITLE 25. HEALTH SERVICES**

### **PART 1. DEPARTMENT OF STATE HEALTH SERVICES**

#### **CHAPTER 300. MANUFACTURE, DISTRIBUTION, AND RETAIL SALE OF CONSUMABLE HEMP PRODUCTS**

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes new §§300.100 - 300.104, 300.201 - 300.203, 300.301 - 300.303, 300.401 - 300.404, 300.501, 300.502, and 300.601 - 300.606 in new Chapter 300, concerning the Manufacture, Distribution, and Retail Sale of Consumable Hemp Products.

#### **BACKGROUND AND PURPOSE**

The purpose of the proposal is to comply with House Bill (H.B.) 1325, 86th Legislature, Regular Session, 2019, which added Texas Health and Safety Code, Chapter 443, relating to the manufacture, distribution, and sale of consumable hemp products.

Under the authority of Texas Health and Safety Code, Chapter 443, the DSHS Hemp Program regulates the manufacture, processing, distribution, and sale of consumable hemp products. Hemp Program regulations are intended to ensure that consumable hemp products are safe to consume and properly labeled. The Hemp Program requires and issues a license for the manufacture, processing, and distribution of consumable hemp products, and a registration of retailers of consumable hemp products.

#### **SECTION-BY-SECTION SUMMARY**

Proposed Subchapter A creates rules related to General Provisions by implementing §300.100, Purpose; §300.101, Definitions; §300.102, Applicability of Other Rules and Regulations; §300.103, Inspections; and §300.104, Manufacture, Processing, Distribution, and Retail Sale of Hemp Products for Smoking.

Proposed Subchapter B creates rules related to Manufacture, Processing, and Distribution of Consumable Hemp Products by implementing §300.201, Application for License or Renewal; §300.202, License Term and Fees; and §300.203, Access to Records.

Proposed Subchapter C creates rules related to the Testing of Consumable Hemp Products by implementing §300.301, Testing Required; §300.302, Sample Analysis of Consumable Hemp and Certain Cannabinoid Oils; and §300.303, Provisions Related to Testing.

Proposed Subchapter D creates rules related to the Retail Sale of Consumable Hemp Products by implementing §300.401, Possession, Distribution and Sale of Consumable Hemp Products; §300.402, Packaging and Labeling Requirements; §300.403, Retail Sale of Out-of-State Consumable Hemp Products; and §300.404, Transportation and Exportation of Consumable Hemp Products Out-of-State.

Proposed Subchapter E creates rules related to the Registration for Retailers of Consumable Hemp Products by implementing §300.501, Registration Required for Retailers of Certain Products and §300.502, Application.

Proposed Subchapter F creates rules related to the Enforcement of Chapter 300 by implementing §300.601, Violation of Department License or Registration Requirement; §300.602, Prohibited Acts; §300.603, Detained or Embargoed Article; §300.604, Destruction of Article; §300.605, Correction by Proper Labeling or Processing; and §300.606, Administrative Penalty.

#### **FISCAL NOTE**

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, enforcement or administration of the rules, there will be an estimated additional cost and

revenue to state government. DSHS does not anticipate a cost to local governments from the implementation of the rules.

The effect on state government for each year of the first five years the proposed rules are in effect is an estimated cost of \$401,008 in fiscal year (FY) 2020; \$598,992 in fiscal year FY 2021; \$1,067,814 in FY 2022; \$1,269,503 in FY 2023; and \$1,499,838 in FY 2024; and an estimated increase in revenue of \$1,200,000 in FY 2020; \$1,475,000 in FY 2021; \$1,807,500 in FY 2022; \$2,194,000 in FY 2023; and \$2,637,500 in FY 2024.

#### GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rules will be in effect:

- (1) the proposed rules will create a government program;
- (2) implementation of the proposed rules will create new DSHS employee positions;
- (3) implementation of the proposed rules will require an increase in future legislative appropriations in FY 2022 - FY 2024;
- (4) the proposed rules will affect fees paid to DSHS;
- (5) the proposed rules create new Hemp Program rules;
- (6) the proposed rules will not expand, limit or repeal any existing rules;
- (7) the proposed rules will increase the number of individuals subject to the rules; and
- (8) the proposed rules will positively affect the state's economy.

#### SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Donna Sheppard, Chief Financial Officer, has determined that there is no anticipated adverse economic effect on small businesses, micro-businesses, or rural communities. The new rules will expand economic opportunity for individuals interested in the manufacture, processing, or retail sale of consumable hemp products.

#### LOCAL EMPLOYMENT IMPACT

The proposed rules will positively affect a local economy.

#### COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas; and the rules are necessary to implement legislation that does not specifically state that §2001.045 applies to the rules.

#### PUBLIC BENEFIT AND COSTS

Stephen Pahl, Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rules are in effect, the public benefit will be the increased opportunity for business owners who are engaged in the manufacture, processing, distribution, and retail sale of consumable hemp products.

Donna Sheppard has also determined that for the first five years the rules are in effect, persons who are required to comply with the proposed rules may incur economic costs due to requirements in the rules for licensure fees and testing of hemp products for an entity engaged in the manufacture, processing, and distribution of consumable hemp, and registration fees for an entity engaged in the sale of consumable hemp products.

## TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does 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, does not constitute a taking under Texas Government Code, §2007.043.

## PUBLIC COMMENT

Questions about the content of this proposal may be directed to Rod Moline, Ph.D., R.S., Section Director, at (512) 231-5712 in the DSHS/CPD Policy, Standards, and Quality Assurance Unit.

Written comments on the proposal may also be submitted to Rod Moline, Ph.D., R.S., Section Director, Mail Code 1987, Texas Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, or by email to DSHSHempProgram@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered at 8407 Wall Street, Austin, Texas 78754 before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 19R074 Hemp Program" in the subject line.

## SUBCHAPTER A. GENERAL PROVISIONS

### 25 TAC §§300.100 - 300.104

#### STATUTORY AUTHORITY

The new rules are authorized by H.B. 1325 that added Texas Health and Safety Code, Chapter 443, which provides that the Executive Commissioner of HHSC may adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 443; and Texas Government Code, §531.0055 and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Health and Safety Code, Chapter 443.

#### §300.100.Purpose.

This chapter implements Texas Health and Safety Code, Chapter 443, regulating the manufacture, distribution, and retail sale of consumable hemp and consumable hemp products in the State of Texas.

#### §300.101.Definitions.

The following words and terms, when used in this chapter, have the following meanings unless context clearly indicates otherwise:

(1) Acceptable hemp THC level--A delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less.

(2) Accredited laboratory--A laboratory accredited in accordance with the International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard.

- (3) Act--House Bill 1325, 86th Legislature, Regular Session, 2019, relating to the production and regulation of hemp in Texas, codified in Texas Health and Safety Code, Chapter 443.
- (4) Analyte--A chemical, compound, element, bacteria, yeast, fungus, mold, or toxin identified and measured by accredited laboratory analysis.
- (5) Approved hemp source--Hemp and hemp products grown for human use and consumption produced under a state or a compatible federal, foreign, or Tribal plan, approved by the United States Department of Agriculture under 7 United States Code (U.S.C.) Chapter 38, Subchapter VII, or Texas Agriculture Code, Chapter 121, or in a manner that is consistent with federal law and the laws of respective foreign jurisdictions.
- (6) Cannabidiol (CBD)--A phytocannabinoid identified as an extract from cannabis plants.
- (7) Certificate of Analysis (COA)--An official document released by the accredited laboratory to the manufacturer, processor, distributor, or retailer of consumable hemp products, the public, or department, which contains the concentrations of cannabinoid analytes and other measures approved by the department, to also include data on levels of THC and state whether a sample passed or failed any limits of content analysis.
- (8) Consumable hemp product (CHP)--Any product processed or manufactured for consumption that contains hemp, including food, a drug, a device, and a cosmetic, as those terms are defined by Texas Health and Safety Code, §431.002, but does not include any consumable hemp product containing a hemp seed, or hemp seed-derived ingredient being used in a manner that has been generally recognized as safe (GRAS) by the FDA.
- (9) Consumable hemp products license--A license issued to a person or facility engaged in the act of manufacturing, extracting, processing, or distributing consumable hemp products for human consumption or use.
- (10) Delta-9 tetrahydrocannabinol (THC)--The primary psychoactive component of cannabis. For the purposes of this chapter, the terms delta-9 tetrahydrocannabinol and THC are interchangeable.
- (11) Department--Department of State Health Services.
- (12) Distributor--A person who distributes consumable hemp products for resale, either through a retail outlet owned by that person or through sales to another retailer. A distributor is required to hold a consumable hemp products license.
- (13) Facility--A place of business engaged in manufacturing, processing, or distributing consumable hemp products subject to the requirements of this chapter and Texas Health and Safety Code, Chapter 431. A facility includes a domestic or foreign facility that is required to register under the Federal Food, Drug, and Cosmetic Act, Section 415 in accordance with the requirements of 21 Code of Federal Regulations Part 1, Subpart H.
- (14) FDA--The United States Food and Drug Administration or its successor agency.
- (15) Federal Act--Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. 301 et seq.).
- (16) Gas chromatography (GC)--A type of chromatography in analytical chemistry used to separate, identify, and quantify each component in a mixture. GC relies on heat for separating and analyzing compounds that can be vaporized without decomposition.
- (17) Good manufacturing practices--Procedures identified and implemented to ensure conformance to the sanitary guidelines recommended by the department with respect to the manufacture and sale of consumable hemp and consumable hemp ingredients, including all provisions as identified and defined in Texas Health and Safety Code, Chapter 431.
- (18) Hemp--The plant, Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the

accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less.

(19) High-performance liquid chromatography (HPLC)--A type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. HPLC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds.

(20) Independent contractor--A person or entity contracted to perform work or sales for a registrant.

(21) License holder--The person who is legally responsible for the operation as a consumable hemp manufacturer, processor, or distributor, and possesses a valid license.

(22) Lot number--A specific quantity of raw or processed hemp product that is uniform and intended to meet specifications for identity, strength, purity, and composition that shall contain the manufacturer's, processor's, or distributor's, number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of consumable hemp products.

(23) Manufacturer--A person who makes, extracts, processes, or distributes consumable hemp product from one or more ingredients, including synthesizing, preparing, treating, modifying or manipulating hemp or hemp crops or ingredients to create a consumable hemp product. For farmers and persons with farm mixed-type facilities, manufacturing and processing does not include activities related to growing, harvesting, packing, or holding raw hemp product.

(24) Measurement of uncertainty--The parameter, associated with the results of an analytical measurement that characterizes the dispersion of the values that could reasonably be attributed to the quantity subjected to testing measurement. For example, if the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis is 0.35% and the measurement of uncertainty is +/- 0.06%, the measured delta-9 tetrahydrocannabinol content concentration level on a dry weight basis for this sample ranges from 0.29% to 0.41%. Because 0.3% is within the distribution or range, the sample is within the acceptable hemp THC level for the purpose of plan compliance.

(25) Non-consumable hemp processor--A person who intends to process hemp products not for human consumption and is registered with the Texas Department of Agriculture.

(26) Non-consumable hemp product--As defined by Texas Agriculture Code, §122.001(8), means a product that contains hemp, other than a consumable hemp product as defined by Texas Health and Safety Code, §443.001. The term includes cloth, cordage, fiber, fuel, paint, paper, particleboard, construction materials, and plastics derived from hemp.

(27) Pathogen--A microorganism of public health significance, including molds, yeasts, *Listeria monocytogenes*, *Campylobacter*, *Salmonella*, *E. coli*, *Yersinia*, or *Staphylococcus*.

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

(29) Process--Extraction of a component of hemp, including CBD or another cannabinoid, that is:

(A) sold as a consumable hemp product;

(B) offered for sale as a consumable hemp product;

(C) incorporated into a consumable hemp product; or

(D) intended to be incorporated into a consumable hemp product.

(30) Processor--A person who operates a facility which processes raw agriculture hemp into consumable hemp products for manufacture, distribution, and sale. A hemp processor is required to hold a consumable hemp products license. A person issued a consumable hemp products license, which only engages in the manufacturing, processing, and distribution of consumable hemp products, is not required to hold a license under Texas Health and Safety Code, Chapter 431, Subchapter J.

(31) QR code--A quick response machine-readable code that can be read by a camera, consisting of an array of black and white squares used for storing information or directing or leading a user to product information regarding manufacturer data and accredited laboratory certificates of analysis.

(32) Raw hemp--An unprocessed hemp plant, or any part of that plant, in its natural state.

(33) Registrant--A person, on the person's own behalf or on behalf of others, who sells consumable hemp products directly to consumers, and who submits a complete registration form to the department for purposes of registering their place of business to sell consumable hemp products at retail to the public.

(34) Reverse distributor--A person registered with the federal Drug Enforcement Agency as a reverse distributor that receives controlled substances from another person or entity for return of the products to the registered manufacturer or to destroy adulterated or impermissible THC products.

(35) Smoking--Burning or igniting a consumable hemp product and inhaling the resultant smoke, vapor, or aerosol.

(36) Tetrahydrocannabinol (THC)--The primary psychoactive component of the cannabis plant.

(37) Texas Department of Agriculture--The state agency responsible for regulation of planting, growing, harvesting, and testing of hemp as a raw agricultural product.

(38) Texas.gov--The online registration system for the State of Texas found at <https://www.texas.gov>.

§300.102. Applicability of Other Rules and Regulations.

Hemp manufacturers, processors, distributors, and retailers must comply with all relevant laws and rules applicable to the manufacture, processing, distribution and sale of consumable products, including:

(1) Chapter 217, Subchapter C of this title (relating to Rules for the Manufacture of Frozen Desserts);

(2) Chapter 229, Subchapter D of this title (relating to Regulation of Cosmetics);

(3) Chapter 229, Subchapter F of this title (relating to Production, Processing, and Distribution of Bottled and Vended Drinking Water);

(4) Chapter 229, Subchapter G of this title (relating to Manufacture, Storage, and Distribution of Ice Sold for Human Consumption, Including Ice Produced at Point of Use);

(5) Chapter 229, Subchapter L of this title (relating to Licensure of Food Manufacturers, Food Wholesalers, and Warehouse Operators);

(6) Chapter 229, Subchapter N of this title (relating to Current Good Manufacturing Practice and Good Warehousing Practice In Manufacturing, Packing, Or Holding Human Food);

(7) Chapter 229, Subchapter W of this title (relating to Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices);

(8) Chapter 229, Subchapter X of this title (relating to Licensing of Device Distributors and Manufacturers); and

(9) Chapter 229, Subchapter GG of this title (relating to Sanitary Transportation of Human Foods).

§300.103.Inspections.

(a) Authorized employees of the department may, upon presenting appropriate credentials to the owner, operator, or person in charge:

(1) enter at reasonable times the premises, conduct inspections, collect samples, and take photographs to determine compliance with this chapter and Texas Health and Safety Code, Chapters 431 and 443;

(2) enter a vehicle being used to transport or hold the consumable hemp product in commerce; or

(3) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the facility or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of this chapter.

(b) The inspection of a facility where consumable hemp products are manufactured, processed, distributed, packed, held or sold, for introduction into commerce shall be for the purpose of determining if the consumable hemp product is:

(1) adulterated or misbranded; or

(2) otherwise manufactured, processed, held, distributed or sold in violation of this chapter or Texas Health and Safety Code, Chapters 431 and 443.

(c) An inspection of a facility in which a prescription drug or restricted device is being manufactured, processed, packed, or held for introduction into commerce under subsection (b) of this section shall not extend to:

(1) financial data;

(2) sales data other than shipment data;

(3) pricing data;

(4) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under this chapter; or

(5) research data other than data:

(A) relating to new consumable hemp products; and

(B) subject to reporting and inspection under regulations issued under §505(i) or (j), §519, or §520(g) of the Federal Act.

(d) An inspection under subsection (b) of this section shall be started and completed with reasonable promptness.

§300.104.Manufacture, Processing, Distribution, and Retail Sale of Hemp Products for Smoking. <

The manufacture, processing, distribution, or retail sale of consumable hemp products for smoking is prohibited.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 23, 2020.

TRD-202001565

Barbara Klein

General Counsel

Department of State Health Services

Earliest possible date of adoption: June 7, 2020

For further information, please call: (512) 231-5653

---

## **SUBCHAPTER B. MANUFACTURE, PROCESSING, AND DISTRIBUTION OF CONSUMABLE HEMP PRODUCTS**

### **25 TAC §§300.201 - 300.203**

#### STATUTORY AUTHORITY

The new rules are authorized by H.B. 1325 that added Texas Health and Safety Code, Chapter 443, which provides that the Executive Commissioner of HHSC may adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 443; and Texas Government Code, §531.0055 and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Health and Safety Code, Chapter 443.

#### §300.201. Application for License or Renewal.

- (a) A person must hold a consumable hemp products license issued by the department before engaging in the manufacture, processing, or distribution of consumable hemp and hemp-derived products.
- (b) A person shall apply for a consumable hemp products license under this subchapter by submitting an application to the department in the manner prescribed by the department for each location engaged in the manufacture, processing, or distribution of consumable hemp products. The application must be accompanied by:
- (1) a legal description of each location to include the global positioning system coordinates for the perimeter of each location:
- (A) where the applicant intends to manufacture or process consumable hemp products; and
- (B) where the applicant intends to store consumable hemp products to include the global positioning system coordinates for the perimeter of each location;
- (2) written consent from the applicant or the property owner, if the applicant is not the property owner, for the department, the Department of Public Safety, and any other state or local law enforcement agency, to enter all premises where consumable hemp is manufactured, processed, or delivered, to conduct a physical inspection or to ensure compliance with this chapter; and
- (3) a fingerprint-based criminal background check from each applicant at the applicant's expense.
- (c) If the applicant or person has been convicted of a felony relating to a controlled substance under federal law or the law of any state within ten years before the date of application, the department shall not issue a consumable hemp products license under this subchapter.



- (d) If the department receives information that a license holder under this subchapter has been convicted of a felony relating to a controlled substance under federal law or the law of any state within ten years before the issue date of the license, the department shall revoke the consumable hemp products license.
- (e) A person who holds a consumable hemp products license under this subchapter shall undergo a fingerprint-based criminal background check at his own expense.
- (f) Applications must contain the following information:
- (1) the name of the license applicant;
  - (2) the business name, if different than applicant name;
  - (3) the mailing address of the business;
  - (4) the street address of the facility;
  - (5) the primary business contact telephone number;
  - (6) the personal email address of the applicant; and
  - (7) the email address of the business, if different than the applicant's email address.
- (g) If a person owns or operates two or more facilities, each facility shall be licensed separately by listing the name and address of each facility on separate application forms.
- (h) Applicants must submit an application for a consumable hemp products license request under this subchapter electronically through Texas.gov. 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.gov.
- (i) All fees required by the department must be submitted with the application.
- (j) Applicants must submit any other information required by the department, as evidenced and provided upon application forms.
- (k) A consumable hemp products license issued by the department should be displayed in an obvious and conspicuous public location within the facility to which the license applies.

*§300.202.License Term and Fees.*

- (a) A consumable hemp product license is valid for one year from the date displayed on the license.
- (b) The department shall issue and renew a license if the license holder:
- (1) is eligible to obtain a license under §300.201 of this subchapter (relating to Application for License or Renewal);
  - (2) submits a license fee to the department;
  - (3) does not owe outstanding fees to the department;
  - (4) possesses testing results of consumable hemp products before their manufacture, distribution, or sale into commerce, and provides those testing results upon department request; and

(5) has not been convicted of a felony relating to a controlled substance under federal law or the law of any state in the ten years before the date of renewal of the license.

(c) Fees.

(1) Before the manufacture, processing, or distribution of consumable hemp products, a license holder must pay a fee of \$250 per facility.

(2) For each facility a license holder must pay:

(A) a \$250.00 fee for amendment to a new license due to a change of ownership of the licensed facility; or

(B) a \$125.00 fee for any amendment during the licensure period due to minor changes, such as change of location, change of name, or change of address.

(3) Fees are not prorated.

(4) A person who files a renewal application after the expiration date of the current license must pay an additional delinquency fee of \$100.

(d) An application for an amendment of a consumable hemp product license is complete when the department has received, reviewed, and found acceptable the application information and fee required by the subsection (c) of this section.

(e) An initial and renewal application for a consumable hemp product license must be processed in accordance with the following time periods:

(1) the first time period of 45 business days begins on the date the department receives a completed application. If an incomplete application is received, the period ends on the date the facility is issued a written notice that the application is incomplete. The written notice shall be issued within 45 business days after receipt of the incomplete application and describe the specific information or fee that is required before the application is considered complete;

(2) the second time period of 45 business days begins on the date the department receives a completed application and ends on the date the license is issued or the facility is issued a written notice that the application is being proposed for denial; and

(3) if the applicant fails to submit the requested information or fee within 135 calendar days after the date the department issued the written notice to the applicant as described in paragraph (1) of this subsection, the application is considered withdrawn.

(f) Reimbursement of fees:

(1) in the event the application is not processed within the time periods stated in subsection (g) of this section, the applicant has the right to make a written request within 30 business days after the end of the second time period that the department shall reimburse in full the fee paid in that application process; and

(2) if the department finds that good cause does not exist for exceeding the established periods, the request shall be denied, and the department shall notify the applicant in writing of the denial of the reimbursement within 30 business days after the department's decision.

§300.203. Access to Records.

(a) A person who is required to maintain records under this chapter or §519 or §520(g) of the Federal Act must maintain records on site for immediate inspection, and at the request of the department, provide access to records for review or copying to verify consumable hemp products are being produced in accordance with United States

Department of Agriculture under 7 United States Code (U.S.C.) Chapter 38, Subchapter VII, or Texas Agriculture Code, Chapter 121.

(b) A person licensed under Texas Agriculture Code, Chapter 122, shall make available to the department upon request the results of tests conducted on samples of hemp or hemp products as evidence that the delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less delta-9 tetrahydrocannabinol concentration of the hemp or hemp products does not exceed 0.3 percent.

(c) Records described in subsection (b) of this section must be maintained for a period of no less than three years after the date the records are created.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 23, 2020.

TRD-202001566

Barbara Klein

General Counsel

Department of State Health Services

Earliest possible date of adoption: June 7, 2020

For further information, please call: (512) 231-5653

## **SUBCHAPTER C. TESTING OF CONSUMABLE HEMP PRODUCTS**

### **25 TAC §§300.301 - 300.303**

#### **STATUTORY AUTHORITY**

The new rules are authorized by H.B. 1325 that added Texas Health and Safety Code, Chapter 443, which provides that the Executive Commissioner of HHSC may adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 443; and Texas Government Code, §531.0055 and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Health and Safety Code, Chapter 443.

#### §300.301. Testing Required.

(a) All hemp or hemp derivatives used in the manufacture of a consumable hemp product must be tested by an accredited laboratory to determine:

- (1) the presence and concentration of cannabinoids;
- (2) the presence and concentration of THC; and
- (3) the presence or quantity of residual solvents, heavy metals, pesticides, and harmful pathogens.

(b) A Certificate of Analysis documenting tests conducted under this subchapter shall:

- (1) be made available to the department upon request in an electronic format before manufacture, processing, or distribution into commerce;
- (2) be in a format that documents presence and content of CBD, and levels of THC; and
- (3) include measurement of uncertainty analysis parameters.

§300.302. Sample Analysis of Consumable Hemp and Certain Cannabinoid Oils.

(a) This section does not apply to low-THC cannabis regulated under Texas Health and Safety Code, Chapter 487.

(b) Notwithstanding any other law, a person shall not sell, offer for sale, possess, distribute, or transport a consumable hemp product in this state, including CBD oil, if the consumable hemp product contains any material extracted or derived from the plant Cannabis sativa L., other than from hemp produced in compliance with 7 United States Code (U.S.C.) Chapter 38, Subchapter VII, unless:

(1) a representative sample of the oil has been tested by an accredited laboratory and found to have a delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less; and

(2) testing results are provided to the department upon request.

(c) The department shall conduct random testing of consumable hemp products at various retail and other facilities that sell or distribute products to ensure the products:

(1) do not contain harmful ingredients;

(2) are produced in compliance with 7 U.S.C. Chapter 38, Subchapter VII; and

(3) have a delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less.

(d) Upon request by the department, the manufacturer, processor, distributor, or retailer of consumable hemp products shall provide representative raw or finished consumable hemp product samples to the department.

(e) Representative raw or finished consumable hemp product samples shall be provided to the department at owner, license holder, or registrant expense.

§300.303. Provisions Related to Testing.

(a) A consumable hemp product that exceeds the acceptable hemp THC level or is adulterated in a manner harmful to human consumption shall not be sold at retail or otherwise introduced into commerce in this state.

(b) A hemp manufacturer, processor, or distributor shall provide the results of testing required by §300.301 of this subchapter (relating to Testing Required) to the department upon request.

(c) The registrant shall provide the testing results required under §300.301 of this subchapter to a consumer or the department upon request.

(d) A license holder shall not use an independent testing accredited laboratory unless the license holder has:

(1) no ownership interest in the accredited laboratory; or

(2) holds less than a ten percent ownership interest in the accredited laboratory if the accredited laboratory is a publicly-traded company.

(e) A license holder must pay the costs of raw and finished hemp product testing in an amount prescribed by the accredited laboratory selected by the license holder.

(f) The department shall recognize and accept the results of a test performed by an accredited laboratory.

(g) The department may require that a copy of the test results be sent directly to the department and the license holder.

(h) The department shall notify the license holder of the results of the test not later than the 14th day after the date testing results are made available to the department.

(i) A license holder shall retain results from samples for a period of no less than three years from the date that testing results are made available to the license holder.

(j) A manufacturer or processor of consumable hemp products shall conduct sampling and testing using acceptance criteria that are protective of public health.

(k) A consumable hemp product is not required to be tested under §300.301 of this subchapter if each hemp-derived ingredient of the product:

(1) has been tested;

(2) includes the results that are available upon request from the department before distribution or sale; and

(3) contains an acceptable hemp THC level.

(l) The department may utilize Table 1 to test raw or finished consumable hemp products:

[Figure: 25 TAC §300.303\(l\) \(.pdf\)](#)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 23, 2020.

TRD-202001567

Barbara Klein

General Counsel

Department of State Health Services

Earliest possible date of adoption: June 7, 2020

For further information, please call: (512) 231-5653

---

## **SUBCHAPTER D. RETAIL SALE OF CONSUMABLE HEMP PRODUCTS**

**25 TAC §§300.401 - 300.404**

STATUTORY AUTHORITY

The new rules are authorized by H.B. 1325 that added Texas Health and Safety Code, Chapter 443, which provides that the Executive Commissioner of HHSC may adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 443; and Texas Government Code, §531.0055 and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Health and Safety Code, Chapter 443.

§300.401.Possession, Distribution, and Sale of Consumable Hemp Products.

A person licensed or registered by the department under this chapter may possess, transport, distribute, or sell a consumable hemp product processed or manufactured in compliance with this chapter.

§300.402.Packaging and Labeling Requirements.

(a) All hemp products marketed as containing CBD must, in addition to the requirements of §300.102 of this chapter (relating to Applicability of Other Rules and Regulations), be labeled in the manner provided by this section with the following information:

(1) lot identification number;

(2) lot date;

(3) product name;

(4) the name of the product's manufacturer;

(5) telephone number and email address of manufacturer; and

(6) a Certificate of Analysis that the delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less.

(b) The label required by this section must appear on each product intended for individual retail sale.

(c) The label required by this section may be in the form of:

(1) a uniform resource locator (URL) for the manufacturer's Internet website that provides or links to the information required by this section; and

(2) a QR code or other bar code that may be scanned and that leads to the information required on the label.

§300.403.Retail Sale of Out-Of-State Consumable Hemp Products.

A registrant selling consumable hemp products processed or manufactured outside of this state must, upon request, submit to the department evidence that the products were processed or manufactured in another state or a foreign jurisdiction in compliance with:

(1) a state or tribal or jurisdiction's plan approved by the United States Department of Agriculture under 7 United States Code (U.S.C.) §1639p;

(2) a plan established under 7 U.S.C. §1639q if that plan applies to the state or jurisdiction; or

(3) the laws of a foreign jurisdiction if the products are tested in accordance with §300.301 of this chapter (relating to Testing Required) and comply with federal regulations.

§300.404. Transportation and Exportation of Consumable Hemp Products Out of State.

Consumable hemp products may be legally transported across state lines and exported to foreign jurisdictions in a manner that is consistent with federal law and the laws of respective foreign jurisdictions.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 23, 2020.

TRD-202001568

Barbara Klein

General Counsel

Department of State Health Services

Earliest possible date of adoption: June 7, 2020

For further information, please call: (512) 231-5653

## **SUBCHAPTER E. REGISTRATION FOR RETAILERS OF CONSUMABLE HEMP PRODUCTS**

### **25 TAC §300.501, §300.502**

#### STATUTORY AUTHORITY

The new rules are authorized by H.B. 1325 that added Texas Health and Safety Code, Chapter 443, which provides that the Executive Commissioner of HHSC may adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 443; and Texas Government Code, §531.0055 and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Health and Safety Code, Chapter 443.

#### §300.501. Registration Required for Retailers of Certain Products.

(a) This section does not apply to:

- (1) low-THC cannabis regulated under Texas Health and Safety Code, Chapter 487; or
  - (2) products recognized by the FDA under 21 CFR Part 182, Substances Generally Recognized as Safe (GRAS).
- (b) A person shall not sell consumable hemp products containing CBD at retail in this state unless the person registers with the department each location owned, operated, or controlled by the person at which those products are sold.

(c) A person is not required to register with the department under subsection (b) of this section if the person is:

- (1) an employee of a registrant; or
- (2) an independent contractor of a registrant who sells the registrant's products at retail.

#### §300.502. Application.

- (a) A person shall register under this subchapter by submitting an application in the manner prescribed by the department.
- (b) Applications must be submitted by the owner, operator, or owner designee and shall contain the following information:
- (1) the name under which the business is operated;
  - (2) the mailing address of the facility;
  - (3) the street address of each location;
  - (4) the primary business contact telephone number;
  - (5) the phone number for each location; and
  - (6) the primary business email address.
- (c) A registration is valid for one year and may be renewed annually, provided the registrant remains in good standing.
- (d) Proof of registration from the department must be prominently displayed in a conspicuous location visible to the public.
- (e) Applicants must submit an application for registration request electronically through [www.Texas.gov](http://www.Texas.gov).
- (f) The department shall collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through [www.Texas.gov](http://www.Texas.gov).
- (g) All fees required by the department must be submitted with the application.
- (1) A retail hemp registration or renewal fee of \$150.00 for each location is required before the sale of consumable hemp product.
  - (2) A person who holds a registration issued by the department under Texas Health and Safety Code, Chapter 443, shall renew the registration by filing an application for renewal on a form authorized by the department accompanied by the appropriate registration fee. A registrant must file for renewal before the expiration date of the current registration. A person who files a renewal application after the expiration date must pay an additional \$100 delinquency fee.
  - (3) Fees are non-refundable.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 23, 2020.

TRD-202001569

Barbara Klein

General Counsel

Department of State Health Services

Earliest possible date of adoption: June 7, 2020



For further information, please call: (512) 231-5653

---

## SUBCHAPTER F. ENFORCEMENT

### 25 TAC §§300.601 - 300.606

#### STATUTORY AUTHORITY

The new rules are authorized by H.B. 1325 that added Texas Health and Safety Code, Chapter 443, which provides that the Executive Commissioner of HHSC may adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 443; and Texas Government Code, §531.0055 and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Health and Safety Code, Chapter 443.

#### §300.601. Violation of Department License or Registration Requirement.

(a) A person commits a violation if the person manufactures, processes, distributes, or sells a consumable hemp product into commerce without a license or registration required by the department under:

(1) §300.201 of this chapter (relating to License Application) for the manufacture, processing, or distributing of consumable hemp products; or

(2) §300.502 of this chapter (relating to Application) for the retail sale of consumable hemp products.

(b) Each day a violation continues or occurs is a separate violation for purposes of imposing an administrative penalty.

#### §300.602. Prohibited Acts.

The following acts, and the causing of the following acts, within this state are unlawful and prohibited:

(1) the distribution in commerce of a consumable hemp product, if such consumable hemp product is contained in a package, or if there is affixed to that consumable hemp product a label that does not conform to the provisions of this chapter; and

(2) the engagement in the packaging or labeling of such consumable hemp products.

#### §300.603. Detained or Embargoed Article.

The department shall affix to an article that is a food, drug, device, cosmetic, or consumer commodity a tag or other appropriate marking that gives notice that the article is, or is suspected of being, adulterated or misbranded and that the article has been detained or embargoed if the department finds or has probable cause to believe that the article:

(1) is adulterated;

(2) is misbranded so that the article is dangerous or fraudulent under this chapter; or

(3) is in violation of Texas Health and Safety Code, §431.084, §431.114, or §431.115.

#### §300.604. Destruction of Article.

(a) The department shall request court-ordered destruction of a sampled, detained, or embargoed consumable hemp product if the court finds the article is misbranded or adulterated.

(b) After entry of the court's order, an authorized agent shall supervise the destruction of the article.

(c) The claimant of the article shall pay the cost of the destruction of the article.

(d) If the article is being destroyed in whole or in part due to a THC content that meets the definition of a schedule I drug, the article must be destroyed by a reverse distributor authorized by the United States Drug Enforcement Agency.

*§300.605. Correction By Proper Labeling or Processing.*

(a) A court may order the delivery of a sampled article or a detained or embargoed article that is adulterated or misbranded to the claimant of the article for labeling or processing under the supervision of the department if:

(1) the decree has been entered in the suit;

(2) the costs, fees, and expenses of the suit have been paid;

(3) the adulteration or misbranding can be corrected by proper labeling or processing; and

(4) a good and sufficient bond, conditioned on the correction of the adulteration or misbranding by proper labeling or processing, has been executed.

(b) The claimant shall pay the costs of department supervision.

*§300.606. Administrative Penalty.*

(a) The department may impose an administrative penalty against a person who holds a license or is registered under this chapter and who violates this chapter.

(b) The department shall notify a retailer of consumable hemp products of a potential violation concerning consumable hemp products sold by the registrant and provide the registrant an opportunity to resolve such violations made unintentionally or negligently within ten business days after the department notifies the registrant.

(c) The department shall assess administrative penalties based upon one or more of the following criteria:

(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of any prohibited acts, and the hazard or potential hazard created to the health, safety, or economic welfare of the public;

(2) the history of previous violations;

(3) the amount necessary to deter future violations;

(4) efforts to correct the violation; and

(5) any other matter that justice may require in relation to the violation.

(d) If the department determines that a violation has occurred, the department shall issue a notice of violation that states the facts on which the determination is based, including an assessment of the penalty.

(e) The notice of violation shall be in writing and sent to the license holder by certified mail. The notice must include a summary of the alleged violation and a statement of the amount of the recommended penalty and must

inform the person that the person has a right to a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(f) Within 20 business days after the date the person receives the notice of violation, the person in writing may accept the determination and recommended penalty of the department or may make a written request for a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(g) If the person accepts the determination and recommended penalty, the department by order shall impose the recommended penalty.

(h) If the person charged with the violation does not respond in writing within 20 business days after the date the person receives the notice of violation, the department shall assess the penalty after determining that a violation occurred and the amount of penalty. The department shall issue an order requiring that the person pay the penalty.

(i) If the person requests a hearing, the department shall refer the matter to the State Office of Administrative Hearings.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 23, 2020.

TRD-202001570

Barbara Klein

General Counsel

Department of State Health Services

Earliest possible date of adoption: June 7, 2020

For further information, please call: (512) 231-5653

---