

## 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 amendments to §§300.100 - 300.103, 300.201 - 300.203, 300.301 - 300.303, 300.402 - 300.404, 300.501, 300.502, 300.601 - 300.606; and new §§300.204 - 300.208, 300.405 - 300.407, 300.701, and 300.702 concerning Manufacture, Distribution, and Retail Sale of Consumable Hemp Products.

##### BACKGROUND AND PURPOSE

House Bill 1325 (86th Legislature, Regular Session) established Texas Health and Safety Code (HSC) Chapter 443 for the Manufacture, Distribution, and Sale of Consumable Hemp Products (CHPs). The rules in Title 25 Texas Administrative Code Chapter 300 implement HSC 443 and became effective on August 2, 2020.

On September 10, 2025, Governor Greg Abbott issued Executive Order GA-56 which directed the department to amend the rules to prohibit the sale of CHPs to minors by retail hemp registrants and manufacturers; to add age verification requirements; to update testing requirements; and to update record keeping requirements.

The proposal increases the initial and renewal licensing fees for consumable hemp manufacturers to \$25,000 annually and increases the registration fees to \$20,000 annually per location. The proposal adds a written consent requirement for Texas Alcoholic Beverage Commission (TABC) to enter the premises to conduct a physical inspection for both manufacturers and retail hemp registrants.

##### SECTION-BY-SECTION SUMMARY

DSHS made minor editorial changes to the rules to ensure consistency and improve overall clarity, including necessary renumbering, punctuation and grammatical edits, and changing the word "shall" to "must."

The proposed amendment to §300.100 is a minor copy edit only.

The proposed amendment to §300.101 changes existing definitions of "approved hemp source," "cannabidiol (CBD)," "Certificate of Analysis (COA)," "consumable hemp product," "consumable hemp products license," "delta-9 tetrahydrocannabinol," "distributor," "manufacturer," "measurement of uncertainty," "non-consumable hemp processor," "registrant," "tetrahydrocannabinol (THC)," and "smoking." The proposed amendment adds new definitions for "batch date," "batch ID number," "cannabis," "decarboxylation," "hemp-derived cannabinoid product," "marihuana," "minor," "private labeling," "supplier," "tetrahydrocannabinol acid (THCA)," "total THC," and "total Delta-9 THC," and removes the definition for "lot number."

The proposed amendment to §300.102 adds Chapter 229, Subchapter O to the list of applicable regulations.

The proposed amendment to §300.103 consists primarily of editorial changes and clarifies citations to 21 United States Code.

The proposed amendment to §300.201 adds Texas Alcoholic Beverage Commission to the list of agencies a consumable hemp product (CHP) license applicant must consent to allow entry and clarifies the requirements for "business name."

The proposed amendment to §300.202 clarifies what constitutes a valid license and updates license fees and terms.

The proposed amendment to §300.203 adds new subsections (d) and (e) to specify what and how records must be maintained and replaces "§519 or §520(g)" with "§360(i) or §360(j)" to reference the correct federal code.

Proposed new §300.204 contains specific requirements for master production records to promote uniformity across production batches.

Proposed new §300.205 contains specific requirements for individual batch production records.

Proposed new §300.206 contains specific source and traceability requirements for raw materials and ingredients.

Proposed new §300.207 contains requirements for conducting product recalls, including maintaining a written recall plan.

Proposed new §300.208 contains requirements for the documentation, evaluation, and investigation of consumer complaints by CHP licensees.

The proposed amendment to §300.301 clarifies testing requirements for raw hemp, hemp-derived ingredients, and CHP and adds new subsections (b) and (d) - (f) which outlines requirements for certificates of analysis (COAs).

The proposed amendment to §300.302 clarifies the language regarding acceptable delta-9 THC limits and business' responsibility for providing samples to DSHS at the businesses' own expense, and changes the title of the rule from *Sample Analysis of Consumable Hemp and Certain Cannabinoid Oils to Sample Analysis of Consumable Hemp Products*.

The proposed amendment to §300.303 clarifies that manufacturers must also meet the testing requirements of §300.301. The proposal repeals subsection (f) regarding DSHS acceptance of sample results from other accredited laboratories, subsection (h) regarding DSHS notification of license holders with sample results within 14 days, and subsection (k) regarding exemptions to testing requirements. The proposed amendment also clarifies the department's responsibility to provide an updated list of analytes and upper limits.

The proposed amendment to §300.402 clarifies label requirements; adds new subsection (b) regarding warning statements on labels; and repeals subsection (c) regarding placement and QR code requirements.

The proposed amendment to §300.403 is a minor edit only replacing "this state" with "Texas," and "registrant" with "person."

The proposed amendment to §300.404 adds language to prohibit the transport of ingredients containing THC above 0.3% into Texas for further processing.

Proposed new §300.405 adds requirements for packaging that is tamper-evident, child-resistant, and non-attractive to children.

Proposed new §300.406 adds language regarding handling of packaging and labeling materials, including keeping written procedures and documentation.

Proposed new §300.407 adds language to prohibit labels that mislead consumers to believe products do not contain hemp-derived cannabinoids or are intended for medical use.

The proposed amendment to §300.501 removes language that restricts the prohibition to products "containing CBD."

The proposed amendment to §300.502 adds language requiring the business or property owner to provide written consent for entry by DSHS, Texas Alcoholic Beverage Commission (TABC), or law enforcement when applying for a license. The amendment also increases fees. Additionally, the amendment specifies that an expired registration is no longer valid and repeals subsection (f) regarding the collection of Texas.gov fees.

The proposed amendment to §300.601 clarifies each violation counts individually when calculating an administrative penalty.

The proposed amendment to §300.602 adds new language to classify the following prohibited acts: refusal of inspection, sample collection, photography, copy of records, and aggressive or threatening behavior.

The proposed amendment to §300.603 is a minor clarifying edit only.

The proposed amendment to §300.604 removes the requirement for a reverse distributor to destroy THC products above the acceptable hemp THC level and instead specifies referral to law enforcement.

The proposed amendment to §300.605 removes a good and sufficient bond for correction of adulterated or mislabeled products and a minor edit.

The proposed amendment to §300.606 is editorial in nature only.

Proposed new §300.701 prohibits the sale of CHPs to minors and requires valid identification as proof of age for purchase.

Proposed new §300.702 establishes sale of CHPs to minors as grounds for the revocation of a CHP license or retail hemp registration.

#### FISCAL NOTE

Christy Havel Burton, Chief Financial Officer, has determined that for each year of the first five years the rules will be in effect, there will be an estimated increase in revenue to state government as a result of enforcing and administering the rules as proposed. Enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of local government.

The effect on state government for each year of the first five years the proposed rules are in effect is an estimated increase in revenue of \$202,050,000 in fiscal year (FY) 2026; \$202,050,000 in FY 2027; \$202,050,000 in FY 2028; \$202,050,000 in FY 2029; and \$202,050,000 in FY 2030; and an estimated increase in costs of \$69,315.00 in FY 2026; \$5,648.00 in FY 2027; \$5,648.00 in FY 2028; \$5,648.00 in FY 2029; and \$5,648.00 in FY 2030.

#### GOVERNMENT GROWTH IMPACT STATEMENT

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

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of DSHS employee positions;

(3) implementation of the proposed rules will require an increase in future legislative appropriations;

(4) the proposed rules will require an increase in fees paid to DSHS;

(5) the proposed rules will create a new regulation;

(6) the proposed rules will expand existing regulations;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) DSHS has insufficient information to determine the proposed rules' effect on the state's economy.

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

Christy Havel Burton has also determined there will be an adverse economic effect on small businesses or micro-businesses, or rural communities due to the higher licensing and registration fees and higher costs to comply with the proposed rule updates.

DSHS estimates the number of small businesses, micro-businesses, and rural communities subject to the proposed rules is approximately 9,900. The projected, total economic impact for small businesses, micro-businesses, and rural communities across the state is \$202,050,000 for each of the first five years the rules will be in effect.

DSHS determined that alternative methods to achieve the purpose of the proposed rules for small businesses, micro-businesses, or rural communities would not be consistent with ensuring the health and safety of adults and minors who have been targeted consumers of CHPs.

#### LOCAL EMPLOYMENT IMPACT

The proposed rules will impact the local economy, but DSHS does not have sufficient data to define the impact.

#### 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.

#### PUBLIC BENEFIT AND COSTS

Timothy Stevenson, DVM, PhD, Deputy 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 increased public health requirements for the manufacturers, distributors, and retailers of CHPs along with prohibited availability and access of CHPs to minors.

Christy Havel Burton 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 because of higher licensing and registration fees. Some retailers and manufacturers may incur costs associated with compliance with age verification requirements, depending on the methodology and equipment used to verify identification and to ensure minors are not sold consumable hemp products.

#### TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to the owner's 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

Written comments on the proposal, including information related to the cost, benefit, or effect of the proposed rule, as well as any applicable data, research, or analysis, may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 4601 West Guadalupe Street, Austin, Texas 78751; or emailed to [HHSRulesCoordinationOffice@hhs.texas.gov](mailto:HHSRulesCoordinationOffice@hhs.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 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 the 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 26R008" in the subject line.

## SUBCHAPTER A. GENERAL PROVISIONS

### 25 TAC §§300.100 - 300.103

#### STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The amendments implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 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 total 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% [0.3 percent] or less.

(2) Accredited laboratory--A laboratory, including at an institution of higher education, accredited in accordance with the Inter-

national 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 must be grown [produced] under a state or [a] compatible federal, foreign, or Tribal plan. These plans must be[;] 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. The products must comply[; or in a manner that is consistent] with federal law and the laws of respective foreign jurisdictions. Additionally, the products must come from a manufacturer or distributor licensed with the department according to Texas Health and Safety Code Chapters 431 and 443.

(6) Batch date--The date a product batch was made, used for tracking and quality control. This is also called the lot date.

(7) Batch ID number--A number that identifies a specific amount of raw or processed hemp product that meets standards for identity, strength, purity, and composition. Each batch ID number must include the manufacturer's, processor's, or distributor's number and a sequence for inventory, traceability, and identification of the plant batches used in making consumable hemp products. This is also called the lot number.

(8) Cannabis--A type of flowering plant in the Cannabaceae family. Cannabis sativa is a species. Cannabis indica and Cannabis ruderalis are subspecies.

(9) [(6)] Cannabidiol (CBD)--A phytocannabinoid produced by [identified as an extract from] cannabis [plants].

(10) [(7)] Certificate of Analysis (COA)--An official document from an [released by the] accredited laboratory available to the manufacturer, processor, distributor, [or] retailer, public, or department. The COA shows the concentrations of cannabinoid analytes and other measurements required by the department, including data on THC levels, and states whether a sample passed or failed content analysis limits. [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.]

(11) [(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. The definition excludes[; but does not include] any [consumable] hemp product containing a hemp seed[;] or hemp seed-derived ingredient that the FDA [being used in a manner that] has designated as Generally Recognized as Safe [been generally recognized as safe] (GRAS) [by the FDA].

(12) [(9)] Consumable hemp products license--A license issued to a person or facility engaged in the act of manufacturing, extracting, or processing[; or distributing] consumable hemp products for human consumption or use.

(13) Decarboxylation--The removal or elimination of a carboxyl group from a molecule or organic compound.

(14) [(10)] Delta-9 tetrahydrocannabinol (d-9 THC)--A tetrahydrocannabinol isomer known as the [The] primary psychoactive component of cannabis. [For the purposes of this chapter, the terms delta-9 tetrahydrocannabinol and THC are interchangeable.]

(15) [(11)] Department--Department of State Health Services.

(16) [(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 wholesaler license per Texas Health and Safety Code Chapter 431 [consumable hemp products license].

(17) [(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.

(18) [(14)] FDA--The United States Food and Drug Administration or its successor agency.

(19) [(15)] Federal Act--Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. 301 et seq.).

(20) [(16)] 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 total 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 total delta-9 tetrahydrocannabinol concentration.

(21) Hemp-derived cannabinoid product--Any intermediate or final product derived from hemp (other than industrial hemp), that:

(A) contains cannabinoids in any form; and

(B) is intended for human or animal use through any means of application or administration, such as inhalation, ingestion, or topical application.

(22) [(17)] Independent contractor--A person or entity contracted to perform work or sales for a registrant.

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

[(19)] 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.]

(24) [(20)] Manufacturer--A person who makes, extracts, processes, packages, repackages, or distributes consumable hemp product from one or more ingredients. The definition includes [, including] synthesizing, preparing, treating, modifying, or manipulating hemp, [or] hemp crops, or ingredients to create a consumable hemp product. It also includes private-labeling. For farmers and persons with farm mixed-type facilities, manufacturing and processing do [does] not include activities related to growing, harvesting, packing, or holding raw hemp product.

(25) Marihuana--The plant Cannabis sativa L., whether growing or not, the seeds of that plant, and every compound, manufacture, salt, derivative, mixture, or preparation of that plant or its seeds. The term does not include:

(A) the resin extracted from a part of the plant or a compound, manufacture, salt, derivative, mixture, or preparation of the resin;

(B) the mature stalks of the plant or fiber produced from the stalks;

(C) oil or cake made from the seeds of the plant;

(D) a compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, fiber, oil, or cake;

(E) the sterilized seeds of the plant that are incapable of beginning germination; or

(F) hemp, as that term is defined by Section 121.001, Agriculture Code.

(26) [(21)] 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 total d-9 THC [delta-9 tetrahydrocannabinol] content concentration level on a dry weight basis is 0.35% and the measurement of uncertainty is +/- 0.06%, the measured total d-9 THC [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.

(27) Minor--A person under 21 years of age.

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

(29) [(23)] 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.

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

(31) [(25)] Person--An individual, business, partnership, corporation, or association.

(32) Private labeling--When a person or manufacturer labels a CHP with the person's name and address, thereby representing itself as responsible for the purity and labeling of a CHP.

(33) [(26)] 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 for incorporation [to be incorporated] into a consumable hemp product.

(34) [(27)] Processor--A person who operates a facility that [which] processes raw agriculture hemp into consumable hemp products for manufacture, distribution, and sale. A hemp processor is re-

quired to hold a consumable hemp products license. A person issued a consumable hemp products license who~~;~~ 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.

(35) [(28)] 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 COA [certificates of analysis].

(36) [(29)] Raw hemp--An unprocessed hemp plant, or any part of the [that] plant, in its natural state.

(37) [(30)] 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 the [their] place of business to sell consumable hemp products at retail to the public.

(38) [(31)] 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.

(39) [(32)] Smoking--Burning or igniting a substance [consumable hemp product] and inhaling the resultant smoke or heating a substance and inhaling the resulting~~;~~ vapor~~;~~ or aerosol.

(40) Supplier--A person or entity that manufactures or processes a material used in the processing or manufacturing of hemp. This term also includes a person or entity that manufactures hemp-derived cannabinoids or sells products containing hemp-derived cannabinoids to retailers.

(41) [(33)] Tetrahydrocannabinol (THC)--A cannabinoid found in cannabis and considered the [The] primary psychoactive component of the cannabis plant.

(42) Tetrahydrocannabinolic acid (THCA)--A precursor to all tetrahydrocannabinols (THC).

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

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

(45) Total THC--The value determined after the process of decarboxylation, or the application of a conversion factor if the testing methodology does not include decarboxylation, that expresses the potential total tetrahydrocannabinol content derived from the sum of all THC isomers and THCA content and reported on a dry weight basis. This technique requires the use of the following conversion: [Total THC = (0.877 x THCA) + THC], which calculates the potential total THC in a given sample.

(46) Total delta-9 THC--The value is determined after decarboxylation or by applying a conversion factor if the testing method does not include decarboxylation. This shows the potential total delta-9 THC content from the sum of delta-9 THC and THCA, reported on a dry weight basis. The post-decarboxylation value of delta-9 THC can be calculated using a chromatograph technique with heat, like gas chromatography, which converts THCA. This test calculates the potential total delta-9 THC in a sample. The total delta-9 THC can also be calculated using a liquid chromatograph technique, which keeps THCA intact. This technique uses the conversion: [Total delta-9 THC = (0.877

x THCA) + delta-9 THC]. This test calculates the potential total delta-9 THC in a sample.]

*§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 O of this title (relating to Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices);

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

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

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

*§300.103. Inspections.*

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

(1) enter [at reasonable times] the premises at reasonable times, 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 a [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, repackaged, sold, or held [or sold], for introduction into commerce must undergo inspection to determine [shall be for the purpose of determining] if the consumable hemp product is:

(1) adulterated or misbranded; or

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

(c) An inspection of a facility where ~~[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 must ~~[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 21 United States Code (U.S.C) §11 or 21 U.S.C. §355 or 21 U.S.C. §360(j) or §360(i) ~~[\$505(i) or (j); §519; or §520(g) of the Federal Act].~~

(d) The inspector must start and complete the ~~[An]~~ inspection under subsection (b) of this section ~~[shall be started and completed]~~ with reasonable promptness.

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 December 15, 2025.

TRD-202504633

Cynthia Hernandez

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Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521



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

### 25 TAC §§300.201 - 300.208

#### STATUTORY AUTHORITY

The amendments and new sections are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The amendments and new sections implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and

Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 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 products.

(b) A person must ~~[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 include ~~[be accompanied by]~~:

(1) a legal description of each location, including ~~[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, Texas Alcoholic Beverage Commission, and any other state or local law enforcement agencies ~~[agency]~~, to enter all premises where consumable hemp is manufactured, processed, or delivered for ~~[, 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 10 ~~[ten]~~ years before the date of application, the department must ~~[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 10 ~~[ten]~~ years before the license was issued ~~[issue date of the license]~~, the department must ~~[shall]~~ revoke the consumable hemp products license.

(e) A person holding ~~[who holds]~~ a consumable hemp products license under this subchapter must ~~[shall]~~ undergo a fingerprint-based criminal background check at the person's ~~[his]~~ own expense.

(f) Applications must contain the following information:

(1) the name of the license applicant;

(2) the business name, if different from the applicant's name, and any other names under which the firm does business, if applicable ~~[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 must have a separate license with its own application form,

[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 [www.Texas.gov](http://www.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 [www.Texas.gov](http://www.Texas.gov).

(i) All fees required by the department must be submitted with the application.

(j) Applicants must provide any additional [submit any other] information required by the department, as specified on the [evidenced and provided upon] application forms.

(k) The facility must display the [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 and must be renewed annually. An expired license is not current or valid. A person must not process hemp or manufacture a consumable hemp product without a valid license.

(b) The department must [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 10 [ten] years before the date of renewal of the license;[-]

(6) submits a complete application; and

(7) has not had a consumable hemp products license revoked for sale to a minor in the preceding five years from the date on which an application is submitted to the department.

(c) Fees.

(1) Before the manufacture, processing, or distribution of consumable hemp products, a license holder must pay a fee of \$25,000 [\$250] per facility. License renewal fees are \$25,000 per facility.

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

(A) a \$25,000 [\$250.00] fee for an 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 license 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 \$1,000 [\$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 calendar [business] days begins on the date the department receives a completed application. If the department receives an incomplete application [is received], the period ends on the date the department issues [facility is issued] a written notice that the application is incomplete. The department must issue the written notice [shall be issued] within 60 calendar [45 business] days after receiving [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 calendar [business] days begins on the date the department receives a completed application and ends on the date the department issues the license [is issued] or issues [the facility is issued] a written notice that the application is being proposed for denial; and

(3) the third time period of 135 calendar days begins on the date [if the applicant fails to submit the requested information or fee within 135 calendar days after the date] the department issues [issued] the written notice to the applicant as described in paragraph (1) of this subsection. If the applicant fails to submit the requested information or fee within this period, the department considers[-] 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 (e) [(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 21 United States Code (U.S.C.) §360(i) or §360(j) [~~§519 or §520(g) of the Federal Act~~] must maintain records on site for immediate inspection. Upon [-] and at the] request by [of] the department, the person must provide access to records for review or copying to verify that consumable hemp products are being produced in accordance with United States Department of Agriculture under 7 U.S.C. [United States Code (U.S.C.)] Chapter 38, Subchapter VII, or Texas Agriculture Code[-] Chapter 121.

(b) A person regulated [licensed] under Texas Agriculture Code[-] Chapter 122 must provide the department with test results of hemp or hemp products upon request. These results must show that the total delta-9 tetrahydrocannabinol content on a dry weight basis, when reported with the accredited laboratory's measure of uncertainty, has a range that includes a result of 0.3% or less.[-] 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 this chapter [subsection (b) of this section] must be maintained for a period of no less than three years after the date the records are created.

(d) A person licensed under this chapter must maintain the following records, as applicable:

(1) COA of raw hemp and hemp ingredients in accordance with §300.301(b)(1) - (3) and §300.301(c) of this chapter;

(2) COA of finished hemp products by batch number;

(3) source of ingredients, including:

(A) receiving records with address and contact information from suppliers, distributors, warehouses, or any person engaged in the business of making a consumer product directly or indirectly; or

(B) licensing documentation from the supplier's respective hemp or food regulating authority;

(4) batch production records;

(5) recalled product information;

(6) consumer complaints;

(7) other records required by the department, including corrective action logs, destruction logs, equipment calibration records, or other accurate reproductions of the original records, or electronic records; and

(8) master production records.

(e) Records must contain actual values and observations. Records must be accurate, permanent, legible, and created concurrently with performance of the activity documented. Records can be electronic. Records must be detailed enough to provide a history of work performed, and include:

(1) the name and, when necessary, the location of the plant or facility;

(2) the date and time of the documented activity, when appropriate;

(3) the signature or initials of the person performing the activity; and

(4) the identity of the product and the batch number.

#### §300.204. Master Production Records.

(a) To ensure uniformity from batch to batch, one person must prepare, date, and sign with full handwritten signature, the master production records for each consumable hemp product, including batch size. A second person must independently check, date, and sign these records. The preparation of master production and control records must be described in a written procedure that the firm must follow.

(b) Master production records must include:

(1) the name and weight or measure of each ingredient;

(2) a complete list of ingredients;

(3) a statement of any calculated excess of a by-product;

(4) an accurate statement of the weight or measure of each ingredient; and

(5) complete manufacturing instructions and specifications.

#### §300.205. Batch Production Records.

Batch production records must be prepared for each batch of consumable hemp product produced and must include complete information regarding each batch. These records must include, if applicable:

(1) the appropriate master product record, checked for accuracy, dated, and signed; and

(2) documentation that each step in the manufacture, processing, packaging, or holding of the batch was accomplished, including:

(A) dates;

(B) identity of individual major equipment and lines used;

(C) weight and measure of ingredients;

(D) in-process results;

(E) laboratory control results, if applicable;

(F) inspection of the packaging and labeling area before and after use;

(G) statement of the actual yield;

(H) complete labeling records, including copies of all labeling used;

(I) any sampling performed;

(J) any investigation conducted;

(K) any destruction of tetrahydrocannabinol; and

(L) any rework conducted.

#### §300.206. Raw Materials and Ingredients.

(a) All raw materials and ingredients must come from approved sources.

(b) All raw materials and ingredients must be clearly identified to allow for appropriate traceability. Identification includes:

(1) name of raw material or ingredient;

(2) batch or lot number from original package;

(3) date the ingredient was manufactured;

(4) date the ingredient was received at the facility;

(5) expiration, re-test, or use-by date; and

(6) total delta-9 THC content concentration level on a dry weight basis.

(c) Substances containing total delta-9 THC levels above the acceptable hemp THC level may not be transported into Texas for further processing within Texas.

#### §300.207. Recalls.

Consumable hemp facilities must establish a written recall plan. This plan must include procedures that describe the steps and assign responsibility for carrying out the following actions, as appropriate to the facility:

(1) directly notify the direct consignees of the hemp product, including how to return or dispose of the affected product;

(2) notify the public about any hazards presented by the product when appropriate to protect public health;

(3) conduct effectiveness checks to verify that the recall is carried out; and



(4) dispose of recalled product appropriately by reprocessing, reworking, diverting to a safe use, or destroying the product.

§300.208. Complaint Files.

(a) Each manufacturer must maintain complaint files relating to product safety. Each manufacturer must establish and maintain procedures for receiving, reviewing, and evaluating complaints. The procedures must ensure that:

(1) all complaints are processed in a uniform and timely manner;

(2) oral complaints are documented upon receipt; and

(3) complaints are evaluated to determine whether the complaint represents an event that must be reported to the FDA and the department.

(b) Each manufacturer must review and evaluate all complaints to determine whether an investigation is necessary. All safety-related complaints must be investigated. If no investigation is made, the manufacturer must maintain a record that includes the reason for not investigating and the name of the individual responsible for the decision.

(c) Any complaint about labeling or packaging not meeting specifications must be reviewed, evaluated, and investigated, unless a similar complaint has already been investigated and another investigation is not needed.

(d) The record of the investigation must include:

(1) the name of the product;

(2) the date the complaint was received;

(3) the batch number and batch date of product used;

(4) the name, address, and phone number of the complainant;

(5) the nature and details of the complaint;

(6) the dates and results of the investigation;

(7) any corrective action taken; and

(8) any reply to the complainant.

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 December 15, 2025.

TRD-202504634

Cynthia Hernandez

General Counsel

Department of State Health Services

Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521



## SUBCHAPTER C. TESTING OF CONSUMABLE HEMP PRODUCTS

**25 TAC §§300.301 - 300.303**

STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The amendments implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 443.

§300.301. Testing Required.

(a) Before a hemp plant is processed or otherwise used in the [All hemp or hemp derivatives used in the] manufacture of a consumable hemp product, a representative sample must be tested [as appropriate for the product and process by an accredited laboratory] to determine:

(1) the [presence and] concentration and identity of the cannabinoids, including all acids in the plant;

(2) the presence and quantity of heavy metals, pesticides, microbial contamination, and other substances prescribed by the department; [and concentration of THC; and]

(3) the presence and concentration of d-9 THC, total d-9 THC, and total THC; and [or quantity of residual solvents, heavy metals, pesticides, and harmful pathogens.];

(4) a total delta-9 tetrahydrocannabinol concentration of 0.3% or less on a dry weight basis.

(b) Before a consumable hemp product, including hemp-derived ingredients used for further processing into another consumable hemp product, is sold at retail, distributed, or otherwise introduced into commerce in this state, a representative sample must be tested to determine:

(1) the presence, concentration, and identity of cannabinoids;

(2) the presence and concentration of d-9 THC, total d-9 THC, and total THC;

(3) the presence and quantity of residual solvents, heavy metals, pesticides, and harmful pathogens; and

(4) the total delta-9 tetrahydrocannabinol concentration is 0.3% or less on a dry weight basis.

(c) [(b)] A COA [Certificate of Analysis] documenting tests conducted under this subchapter must [shall]:

(1) be made available to the department upon request in an electronic format before manufacture, processing, or distribution into commerce; and

(2) include measurement of uncertainty analysis parameters.

(d) The COA must contain, at a minimum, the following information:

- (1) laboratory name, address, and contact information;
- (2) hemp cultivator or hemp manufacturer's name and address;
- (3) sampler identification;
- (4) sample identifying information, including matrix type;
- (5) lot identification number of sample;
- (6) sample received date and the dates of sample analyses and corresponding testing results;
- (7) units of measure;
- (8) analytical methods, analytical instrumentation used, and corresponding limits of detection (LOD) and limits of quantitation (LOQ);
- (9) expiration date;
- (10) QR code on the COA verifying the authenticity of testing conducted at an accredited laboratory;
- (11) measurement of uncertainty analysis parameters; and
- (12) results of all requested analyses performed for the sample, including percentage of delta-9 THC, total delta-9 THC, and total THC per container.

(e) It is a violation if a person, with the intent to deceive, forges, falsifies, or alters the results of a laboratory test authorized or required by this chapter. Consumable hemp products found in violation of this subsection must be retested and are subject to detention or embargo under Texas Health and Safety Code §431.048.

(f) Expired COAs are not valid. Consumable hemp products with expired COAs must be retested and are subject to detention or embargo under Texas Health and Safety Code §431.048.

*§300.302. Sample Analysis of Consumable Hemp Products [and Certain Cannabinoid Oils].*

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

(b) Regardless of [Notwithstanding] any other law, a person must [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, and [unless]:

(1) a representative sample of the consumable hemp product [oil] has been tested by an accredited laboratory and found to have a total delta-9 THC [tetrahydrocannabinol content] concentration of 0.3% or less [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% [0.3 percent] or less; and

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

(c) The department must [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 total delta-9 THC [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% [0.3 percent] or less.

(d) Upon request by the department, the manufacturer, processor, distributor, or retailer of consumable hemp products must [shall] provide representative raw or finished consumable hemp product samples to the department. These samples must be provided at the licensee's or registrant's expense.

~~[(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 must [shall] not be sold at retail or otherwise introduced into commerce in this state.

(b) A hemp manufacturer, processor, or distributor must [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 and manufacturer must [shall] provide the testing results required under §300.301 of this subchapter to a consumer or the department upon request.

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

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

(2) holds 10 [less than a ten] percent or less ownership interest in the accredited laboratory if the accredited laboratory is a publicly traded [publicly-traded] company.

(e) A license holder or registrant 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, including at an institution of higher education.]~~

~~[(g)] [(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.]~~

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

(h) ~~[(j)]~~ A manufacturer or processor of consumable hemp products must [shall] conduct sampling and testing using acceptance criteria determined by the department [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.]~~

(i)(4)] The licensee or registrant must ensure all products are tested for the most current list of analytes maintained by the department. [department may utilize Table 1 to test raw or finished consumable hemp products as appropriate for the product and the process:] [Figure: 25 TAC §300.303(4)]

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 December 15, 2025.

TRD-202504635

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Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521



## SUBCHAPTER D. RETAIL SALE OF CONSUMABLE HEMP PRODUCTS

### 25 TAC §§300.402 - 300.407

#### STATUTORY AUTHORITY

The amendments and new sections are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The amendments and new sections implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 443.

#### §300.402. *Packaging and Labeling Requirements.*

(a) All consumable hemp products marketed as containing ~~[more than trace amounts of]~~ cannabinoids 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) ~~batch [lot]~~ number;
- (2) ~~batch [lot]~~ date;
- (3) product name;
- (4) ~~[the]~~ name of the product's manufacturer;
- (5) telephone number and email address of manufacturer;

[and]

(6) a uniform resource locator (URL) that provides or links to a COA for the product or each hemp-derived ingredient of the product, including the amount of cannabinoid in each serving or unit of the

product, the amount of total THC, and total delta-9 THC. The URL must: [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.]

(A) be conspicuously marked; and

(B) directly link to a webpage where the required COA may be found in three or fewer steps; and

(7) recommended serving size in milligrams and servings per container.

(b) Labels must include the following specific warnings:

(1) keep out of reach of children;

(2) product may contain tetrahydrocannabinol (THC) and can cause a user to fail a drug test;

(3) all THC's have psychoactive properties that may produce an effect similar to or greater than the effect of marijuana, a controlled substance;

(4) pregnant or nursing women should consult a healthcare provider before use; and

(5) this product has not been evaluated by the FDA.

(c) ~~[(b)]~~ The label required by this section must appear on the outer packaging of each product intended for individual retail sale.

~~[(e) 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 person ~~[registrant]~~ selling consumable hemp products processed or manufactured outside of Texas ~~[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. Substances containing total delta-9 THC levels above the acceptable hemp THC level may not be transported into Texas for further processing within Texas.

#### §300.405. *Packaging Requirements.*

(a) Before selling or distributing a consumable hemp product, the product must be prepackaged or, at the time of sale, placed in packaging or a container that is:

(1) tamper-evident;

(2) child resistant; and

(3) resealable, if the product contains multiple servings or includes multiple products purchased in one transaction, while keeping the child-resistant mechanism to remain intact.

(b) It is prohibited to market, advertise, sell, or cause to be sold an edible consumable hemp product containing a hemp-derived cannabinoid that:

(1) is in the shape of a human, animal, or cartoon or in another shape that is attractive to children; or

(2) is in packaging or a container that:

(A) is in the shape of a human, animal, or cartoon or in another shape that is attractive to children;

(B) depicts an image of a human, animal, or cartoon or another image that is attractive to children;

(C) imitates or mimics trademarks or trade dress of products that are or have been primarily marketed to minors;

(D) includes a symbol that is primarily used to market products to minors; or

(E) includes an image of a celebrity.

(c) In this section, a cartoon includes a depiction of an object, person, animal, creature, or any similar caricature that:

(1) uses comically exaggerated features and attributes;

(2) assigns human characteristics to animals, plants, or other objects; or

(3) has unnatural or extra-human abilities, such as imperiousness to pain or injury, x-ray vision, tunneling at very high speeds, or transformation.

§300.406. Packaging and Labeling Control.

(a) There must be clear written procedures describing in sufficient detail the process for receipt, identification, storage, handling, and examination of labeling and packaging materials.

(b) Labeling and packaging materials must be examined upon receipt and before use in packaging or labeling of a consumable hemp product. All labels and packaging material meeting appropriate written criteria must be approved by a qualified individual as defined in 25 TAC §229.211(54) (relating to Definitions), and released for use. Any labeling or packaging materials that do not meet such criteria must be rejected to prevent use in unsuitable operations.

(c) Records must be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected.

(d) Obsolete or rejected labeling and other packaging must be destroyed.

(e) Labeling materials issued for a batch must be carefully examined for identity and conformity to the labeling specified in the master production records.

(f) Labeling not currently being applied must be stored in a manner to prevent mix-ups with active labeling and ensure appropriate use.

§300.407. Misleading Consumable Hemp Packaging.

A person must not sell or offer for sale a consumable hemp product that contains or is marketed as containing hemp-derived cannabinoids in a package that depicts any statement, artwork, or design that would likely mislead a person to believe:

(1) the package does not contain a hemp-derived cannabinoid; or

(2) the product is intended for medical use.

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 December 15, 2025.

TRD-202504636

Cynthia Hernandez

General Counsel

Department of State Health Services

Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521



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

### 25 TAC §300.501, §300.502

#### STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The amendments implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 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 approved by the FDA, or recognized by the FDA under 21 Code of Federal Regulations [CFR] Part 182, Substances Generally Recognized as Safe (GRAS).

(b) A person must ~~shall~~ not sell consumable hemp products ~~[containing CBD]~~ at retail in Texas ~~[this state]~~ unless the person registers ~~[with the department]~~ each location ~~with the department~~. This includes any location owned, operated, or controlled by the person ~~where consumable hemp~~ ~~[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 must ~~[shall]~~ register under this subchapter by submitting an application in the manner prescribed by the department.

(b) The owner, operator, or owner designee [Applications] must submit an application that contains [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; ~~and[-]~~

(7) the written consent from the applicant or property owner, if the applicant is not the property owner, for the department, Department of Public Safety, Texas Alcoholic Beverage Commission, and other state or local law enforcement agencies to enter all premises where consumable hemp is manufactured, processed, or delivered for physical inspection or to ensure compliance with this chapter.

(c) A registration is valid for one year and may be renewed annually, provided the registrant remains in good standing. An expired registration is not current or valid. A person must not sell at retail or offer for sale at retail a consumable hemp product without a current and valid registration.

(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.]~~

~~[(f) [(g)] All fees required by the department must be submitted with the application.~~

(1) A retail hemp registration or renewal fee of \$20,000 ~~[\$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 must ~~[; shall]~~ renew the registration by filing an application for renewal on a form authorized by the department with ~~[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 \$1,000 ~~[\$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 December 15, 2025.

TRD-202504637

Cynthia Hernandez

General Counsel

Department of State Health Services

Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521



## SUBCHAPTER F. ENFORCEMENT

### 25 TAC §§300.601 - 300.606

#### STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The amendments implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 443.

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

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

(1) §300.201 of this chapter (relating to Application for License or Renewal) 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 counts as [is] a separate violation when calculating ~~[for purposes of imposing]~~ an administrative penalty.

*§300.602. Prohibited Acts.*

The following acts, and the causing of the following acts, within Texas ~~[this state]~~ are unlawful and prohibited:

(1) introducing hemp-derived cannabinoids into commerce ~~[the distribution in commerce of a packaged consumable hemp product, if there is affixed to that consumable hemp product a label] that do~~ ~~[does]~~ not conform to the provisions of this chapter;~~[ and]~~

(2) engaging in the packaging or labeling of packaged consumable hemp products if there is affixed to the consumable hemp product a label that does not conform to the provisions of this chapter;~~[-]~~

(3) refusing to permit the following:

(A) entry or inspection;

(B) taking of a sample;

(C) access to or copying of any record as authorized by Texas Health and Safety Code §431 and this chapter; or

(D) photography for inspection purposes; and

(4) refusing to permit inspection, which includes impeding the inspection, aggressive behaviors, using foul language, or exhibiting threatening behavior.

*§300.603. Detained or Embargoed Article.*

The department must attach a tag or other appropriate marking [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. The department will tag or mark any [and that the article has been] detained or embargoed article 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 may [shall] request court-ordered destruction of a sampled, detained, or embargoed consumable hemp product if the department [court] finds the article is misbranded or adulterated.

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

(c) The claimant of the article must [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 controlled substance [schedule I drug], the department may refer to the appropriate law enforcement agency. The article must be destroyed per department specifications and documented as such, unless law enforcement communicates an intent to use the article for evidence [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; and

(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 must [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 must [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 unintentional or negligent [such] violations [made unintentionally or negligently within ten business days] after being notified by the department [notifies the registrant].

(c) The department assesses [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) the 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 must [shall] issue a notice of violation. The notice must state [that states] the facts on which the determination is based. The notice must include [including] an assessment of the penalty.

(e) The notice of violation must [shall] be in writing and be sent to the license holder or registrant 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 of [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 imposes [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 determines that a violation occurred and assesses [shall assess] the penalty [after determining that a violation occurred and the amount of penalty]. The department must [shall] issue an order requiring that the person pay the penalty.

(i) If the person requests a hearing, the department refers [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 December 15, 2025.

TRD-202504638

Cynthia Hernandez

General Counsel

Department of State Health Services

Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521

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## SUBCHAPTER G. RESTRICTIONS ON SALE TO MINORS

### 25 TAC §300.701, §300.702

#### STATUTORY AUTHORITY

The new sections are authorized by Texas Health and Safety Code §1001.075, which authorizes the executive commissioner of HHSC to 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; Texas Health and Safety Code §12.001, stating that the executive commissioner of HHSC has general supervision and control over all matters relating to the health of Texas citizens; Texas Health and Safety Code Chapter 431 and §443.051, stating that the executive commissioner of HHSC shall adopt rules governing the provision of CHPs by license and registration holders; Texas Government Code §524.0151 and §524.0005; and Texas Health and Safety Code §12.001.

The new sections implement Texas Government Code §524.0151, Texas Government Code §524.0005, Texas Health and Safety Code §1001.075, Texas Health and Safety Code §12.001, and Texas Health and Safety Code Chapters 431 and 443.

#### §300.701. Restriction on Sale to Minors.

(a) It is prohibited to deliver, market, advertise, sell, or cause to be sold a consumable hemp product (CHP) containing a hemp-derived cannabinoid to a minor.

(b) A person who sells CHP must verify each purchaser's age by reviewing a valid proof of identification before completing the sale of any CHP.

(c) A valid proof of identification may include a driver's license issued by Texas or another state, a passport, or an identification card issued by a state or the federal government. A valid proof of identification must meet the following criteria:

- (1) include a physical description and a photograph that matches the person's appearance;
- (2) provide the individual's date of birth;
- (3) be issued by a government agency; and
- (4) is not expired.

#### §300.702. Grounds for Consumable Hemp License or Retail Hemp Registration Revocation.

(a) The department may, after providing an opportunity for a hearing, revoke a consumable hemp license or retail hemp registration after determining the license or registration holder, or an employee, sold, served, or delivered a consumable hemp product to a minor.

(b) An exception to subsection (a) of this section exists where the minor falsely represents to be at least 21 years of age by displaying an apparently valid proof of identification.

(c) The department may impose penalties and pursue additional enforcement actions as provided under Texas Health and Safety Code Chapters 431 and 443.

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 December 15, 2025.

TRD-202504639

Cynthia Hernandez

General Counsel

Department of State Health Services

Earliest possible date of adoption: January 25, 2026

For further information, please call: (512) 719-3521



## TITLE 37. PUBLIC SAFETY AND CORRECTIONS

### PART 11. TEXAS JUVENILE JUSTICE DEPARTMENT

#### CHAPTER 341. GENERAL STANDARDS FOR JUVENILE PROBATION DEPARTMENTS

The Texas Juvenile Justice Department (TJJD) proposes to amend 37 TAC, Part 11, §341.202, Policies and Procedures; §341.302, Participation in Community Resources Coordination Groups; and §341.502, Risk and Needs Assessment.

#### SUMMARY OF CHANGES

As required due to statutory changes, amendments to §341.202 will include: 1) adding a subparagraph titled *Diversion of Juveniles in a General Residential Operation* to the list of topics that departments must address in their policies and procedures and provide information related to including each of those specific topics; 2) removing the subparagraph titled *Deferred Prosecution* related to fees from the list of topics that departments must address in their policies and procedures; 3) providing that, if a probation department uses volunteers or interns, the juvenile board must establish policies that include a requirement to conduct criminal history searches and non-criminal background searches in accordance with 37 TAC, Part 11, Chapter 344 for volunteers and interns who will have direct, unsupervised access to juveniles or direct contact with a juvenile and prohibiting such contact if the person does not meet the requirements in Chapter 344; and 4) adding a subparagraph titled *Training Requirements* to the list of topics that departments must address in their policies and procedures and providing information related to including each of those specific topics. (The topics that must be trained are related to maintaining professional relationships with children and recognizing and reporting suspected physical and sexual abuse.)

As required due to a non-substantive statutory revision, amendments to §341.302 will include modifying a statutory reference related to participation in a community resources coordination group.

As required due to statutory changes, amendments to §341.502 will include adding that, prior to the disposition of a juvenile's case, a probation department must screen the juvenile for risk of commercial sexual exploitation.

#### FISCAL NOTE

Emily Anderson, Deputy Executive Director: Support Operations and Finance, has determined that, for each year of the first five years the amended sections are in effect, there will be no significant fiscal impact for state government or local governments as a result of enforcing or administering the sections.

#### PUBLIC BENEFITS/COSTS