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Proposed Rulemaking Action

Agency Code: 0201

Title 37: Public Safety and Corrections

Part 1: Texas Department of Public Safety

Chapter: 12. Compassionate-Use/Low-THC Cannabis Program

Subchapter: A. General Provisions

Division:

TAC Section Number(s): §§12.1 – 12.4, 12.7 – 12.9

New  Amendment  Repeal

Does this filing have adoption by reference material associated with it?  Yes  No

Common preamble:  Yes  No

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Graphics File Name:  
(Place name of graphics file in the comment section.)

Verification/Certification

I verify that I have reviewed the submitted document and that it conforms to all applicable Texas Register filing requirements. The submitted document has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Agency Liaison: Duncan R. Fox or Susan Estringel

Certifying Official: D. Phillip Adkins

Title: General Counsel

Signature:

Date of Verification:

Phone Number for public inquires about submission: (512) 424-5848

The Texas Department of Public Safety (the department) proposes amendments to §§12.1 – 12.4, 12.7, 12.8 and proposed new §12.9, concerning General Provisions. These amendments are necessary to clarify and enhance certain safety and security requirements and to provide a requirement that dispensers obtain certain levels of commercial liability insurance coverage. Proposed new §12.9 provides more specific product testing and waste disposal requirements.

Suzy Whittenton, Chief Financial Officer, has determined that for each year of the first five-year period these rules are in effect there will be no fiscal implications for state or local government, or local economies.

Ms. Whittenton has determined that there will be no adverse economic effect on small businesses or micro-businesses required to comply with the proposed amendments to §§12.1, 12.3, 12.4, 12.5, 12.6, 12.8, and 12.9. There is no anticipated economic cost to businesses required to comply with these rules as proposed. There is no anticipated negative impact on local employment.

Ms. Whittenton has also determined that §§12.2 and 12.7 may have adverse economic effects on small businesses required to comply with these rules as proposed. The department estimates there will be three licensees, all of these licensees will be small businesses. These estimates are based on an analysis of other states' compassionate-use programs and the number of patients in Texas with intractable epilepsy, and Texas Health and Safety Code Chapter 487's requirements that the department issue at least three licenses and that issuance of the license be necessary to ensure reasonable statewide access to, and the availability of low-THC cannabis for patients for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code. The department estimates the projected impact of these rules will be increased costs of compliance associated with liability insurance coverage and production related safety standards. Specifically, the department estimates §12.2's requirement that dispensers obtain commercial liability insurance coverage will likely cost \$4,000 to \$5,000 per year. Its requirement that dispensers have a fire alarm and fire extinguishing system will impose costs, depending on the size and complexity of dispenser's structures. The department estimates a basic fire alarm system with smoke and heat detectors, and alarms with both visual and audio alerts, will cost \$1 to \$2 per square foot. More complex systems in large buildings may cost \$3 to \$6 per square foot. A sprinkler or other extinguishing system may cost \$3 to \$12 per square foot, not including installation. Monitoring fees may cost \$50 to \$60 per month.

Section 12.7 requirement of a ventilation system with the capability to detect and signal problematic exhaust levels for the extraction room, are estimated to cost approximately \$5,000 for those dispensers using CO2 systems and \$15,000 for butane based systems. The requirement of an emergency power backup system will vary considerably with the size of the facility, but the department would estimate a backup generator to cost \$3,000 to \$15,000.

In preparing these rules the department considered the alternatives of granting exemptions or grace periods from the requirements for small and micro businesses. However, these rules are intended to implement Texas Health and Safety Code, Chapter 487's requirements that licensees possess the technical and technological ability to cultivate and produce low-THC cannabis; the ability to secure the necessary resources, personnel, and facilities; the ability to maintain accountability for the raw materials, the finished product, and any by-products used or produced

in the cultivation or production of low-THC cannabis to prevent unlawful access to or unlawful diversion or possession of those materials, products, or by-products; and the financial ability to maintain operations for not less than two years. The department's proposals reflect the minimum standards necessary to ensure the health, safety, and the environmental and economic welfare of the state. The department is not authorized to create grace periods or other exemptions from the statutory requirements, reflected in Texas Health and Safety Code, §487.102. Moreover, an exemption or grace period would be inconsistent with the health, safety, or environmental and economic welfare of the state. There is no anticipated negative impact on local employment.

In addition, Ms. Whittenton has also determined that for each year of the first five-year period the rules are in effect, the public benefit anticipated as a result of enforcing the rules will be greater protection of the public against potentially unsafe production methods or negative environmental impacts, and reduction in the potential for diversion of marijuana or related products.

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

The department has determined that Chapter 2007 of the Texas Government Code does not apply to this proposal. Accordingly, the department is not required to complete a takings impact assessment regarding this proposal.

Comments on this proposal may be submitted to Steve Moninger, Regulatory Services Division, Department of Public Safety, P.O. Box 4087, MSC-0240, Austin, Texas 78773-0246, or by email at <https://www.dps.texas.gov/rsd/contact/default.aspx>. Select "Compassionate Use Program". Comments must be received no later than thirty (30) days from the date of publication of this proposal.

This proposal is proposed pursuant to Texas Government Code, §411.004(3), which authorizes the Public Safety Commission to adopt rules considered necessary for carrying out the department's work, and Texas Health and Safety Code, §487.052, which requires the department adopt rules necessary for the administration and enforcement of Texas Health and Safety Code, Chapter 487.

Texas Government Code, §411.004(3) and Texas Health and Safety Code, §487.052 are affected by this proposal.

<rule>

§12.1. Definitions.

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

- (1) Act--Texas Health and Safety Code, Chapter 487.
- (2) Application--Includes an original application for a registration or license, or an application to renew a registration or license, issued under the Act.
- (3) Department--The Texas Department of Public Safety.
- (4) Director--An individual [, including any owner,] involved in decisions governing the operation or daily functions of the licensed dispensing organization, and any owner, partner, or shareholder of the business.
- (5) Dispensing organization--An organization licensed to perform the regulated functions of cultivation, processing, and dispensing of low-THC cannabis.
- (6) Employee--An individual engaged by or contracting with a licensee to assist with any regulated function, whether or not compensated by salary or wage.
- (7) Licensee--An organization licensed under the Act.
- (8) Manager--An individual employed or otherwise engaged by a dispensing organization to supervise others in any portion of the regulated functions and processes.
- (9) Prescription--An entry in the compassionate-use registry that meets the requirements of Texas Occupations Code, Chapter 169.
- (10) Product--Any form of low-THC cannabis that is cultivated, handled, transported, processed, or dispensed, or raw materials used in or by-products created by the production or cultivation of low-THC cannabis.
- (11) Registrant--An individual registered with the department as a director, manager, or employee of a licensee; this term does not include a physician registered as a prescriber of low-THC cannabis.
- (12) Regulated premises--The physical areas under the control of a licensee, in which low-THC cannabis, or production related raw materials or by-products, are [is] cultivated, handled, transported, processed, or dispensed.
- (13) SOAH--State Office of Administrative Hearings.

§12.2. Requirements and Standards.

(a) A licensee [Licensees] may only perform [provide] regulated functions [services] at a [the] department approved location [locations]. Any change in location must be approved by the department prior to operation in a regulated capacity.

(b) Licensees shall notify the department within five (5) business days of a registrant's termination of employment.

(c) All licensees shall display in a conspicuous location [in the principal place of business and in any branch location] a copy of the department issued license and information on how to submit a complaint to the department.

(d) Licensees must establish and implement a drug-free workplace policy consistent with the Texas Workforce Commission's "Drug-Free Workplace Policy," and shall maintain in each registrant's file a copy of the company's policy signed or otherwise acknowledged by the registrant.

(e) Licensees and registrants must cooperate fully with any inspection or investigation conducted by the department, or by a state fire marshal, or local designee of the state fire marshal, including but not limited to the provision of any laboratory test results, employee records, [or] inventory and destruction records, or other records required under the Act or this chapter, and the compliance with any subpoena issued by the State of Texas [department].

(f) Licensees and registrants may not cultivate, process, or dispense low-THC cannabis or possess any raw material used in or by-product created by the production or cultivation of low-THC cannabis if the respective license or registration has expired, or has been suspended or revoked.

(g) Licensees and registrants may not dispense to an individual other than a [qualified] patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code, or the [a qualified] patient's legal guardian [representative].

(h) Licensees and registrants may not permit or fail to prevent the diversion of any controlled substance.

(i) Those registered with the department as directors, managers, or employees of a licensed dispensing organization may only perform functions [services] regulated under the Act for the licensee(s) [licensee] with whom they are registered.

(j) If arrested, charged, or indicted for a criminal offense above the level of Class C misdemeanor, a registrant shall within seventy-two (72) hours notify the employing licensee. [,] When [and the employer when] notified by the registrant [employee] or otherwise informed, the licensee shall notify the department in writing (including by email) within seventy-two (72) hours of notification. The notification shall include the name of the arresting agency, the offense, court, and cause number of the charge or indictment. The registrant and licensee must supplement their respective notifications as further information becomes available.

(k) Registrants must carry on their person or otherwise display their department issued registration card while performing any functions [services] regulated under the Act involving contact with or exposure to patients or the general public, including the dispensing of low-THC cannabis to patients and the transportation of low-THC cannabis on behalf of a licensee.

(l) All advertisements for functions [services] regulated under the Act must contain the dispensing organization's license number in a font of the same size as the primary text of the advertisement.

(m) Licensees must comply with all applicable local, state and federal regulations and permitting requirements relating to air and environmental quality, advertising, business and occupancy, building, plumbing, electrical, fire safety, [and] noise, and odor or other nuisances. This section does not require compliance with a regulation that conflicts with the Act or this chapter.

[(n) Destruction of any waste products related to the cultivation or processing of low-THC cannabis must involve the rendering of the product indistinguishable from other non-cannabis related plant material. The waste product must be stored in a locked container prior to disposal.]

(n) [(o)] Licensees must use applicable best practices to limit contamination of the product including but not limited to residual solvents, metals, mold, fungus, bacterial diseases, rot, pests, pesticides, mildew, and any other contaminant identified as posing potential harm. [The licensee shall maintain quality history records showing any laboratory testing results conducted on the licensee's products.]

(o) [(p)] Licensees must have a plan for establishing a recall of their products in the event a product is shown by testing or other means to be, or potentially to be, defective or have a reasonable probability that their use or exposure to will cause [serious] adverse health consequences. At a minimum, the plan should include the method of identification of the products involved; notification to the processing or dispensing organization or others to whom the products were sold or otherwise distributed; and how the products will be disposed of if returned to or retrieved by the licensee.

(p) Licensees shall retain the registration card of all terminated registrants for one year after termination, unless the card is seized or destroyed by department personnel.

(q) Licensees shall maintain commercial general liability insurance coverage, as described in §12.11 of this title (relating to Application for License), and maintain current proof of such insurance on file with the department.

(r) Licensees' regulated premises must annually pass an inspection conducted by the state fire marshal or local designee of the state fire marshal. Proof of the passing inspection must be submitted to the department on a form approved by the department.

(s) Licensees' regulated premises shall be protected by a fire alarm and sprinkler system that complies with local ordinances and applicable Texas Department of Insurance administrative rules, 28 TAC Chapter 34, concerning State Fire Marshal.

(t) Licensees shall install an exterior wall-mounted building key safe at the main entrance to any processing facility, to enable emergency access for fire departments and emergency medical services.

(u) To the extent there is a conflict between the requirements of this chapter, or a conflict between this chapter and the Act, the more restrictive requirement governs. To the extent any requirement of this chapter or the Act conflicts with a regulation incorporated herein, this chapter or the Act shall govern.

(v) Research or development beyond that which is necessary for the cultivation or production of low-THC cannabis is prohibited.

(w) Cultivation of plants other than marijuana plants to be processed for low-THC cannabis is prohibited.

(x) Only low-THC cannabis may be dispensed or sold. By products must be destroyed.

(y) Any interstate transportation of low-THC cannabis or raw materials used in or by-products created by the production of low-THC cannabis must comply with federal law.

(z) Registrants must be at least twenty-one (21) years of age at the time of application.

### §12.3. Criminal History Disqualifiers.

(a) Registration as a director, manager or employee of a licensed dispensing organization provides these individuals access to sensitive medical information, drugs, and the equipment and raw materials needed to produce drugs. Registration provides those predisposed to commit fraud, theft and drug related crimes with greater opportunities to engage in such conduct and escape detection or prosecution. Therefore, the department has determined that offenses of the types detailed in subsection (b) of this section directly relate to the duties and responsibilities of those who are registered under the Act. Such offenses include crimes under the laws of another state or the United States, if the offense contains elements that are substantially similar to the elements of an offense under the laws of this state. Such offenses also include those "aggravated" or otherwise enhanced versions of the listed offenses.

(b) The list of offenses in this subsection is intended to provide guidance only and is not exhaustive of either the offenses that may relate to the regulated occupation or of those independently disqualifying under Texas Occupations Code, §53.021(a)(2) - (4). The listed offenses are general categories that include all specific offenses within the corresponding chapter of the Texas Penal Code and Texas Health and Safety Code. In addition, after due consideration of the circumstances of the criminal act and its relationship to the position of trust involved in the particular licensed occupation, the department may find that an offense not described in this subsection also renders an individual unfit to hold a registration. In particular, an offense that is committed in one's capacity as a registrant under the Act, or an offense that is facilitated by one's

registration under the Act, will be considered related to the regulated occupation and may render the individual unfit to hold the registration.

- (1) Bribery--Any offense under the Texas Penal Code, Chapter 36.
- (2) Burglary and criminal trespass--Any offense under the Texas Penal Code, Chapter 30.
- (3) Fraud--Any offense under the Texas Penal Code, Chapter 32.
- (4) Perjury--Any offense under the Texas Penal Code, Chapter 37.
- (5) Robbery--Any offense under the Texas Penal Code, Chapter 29.
- (6) Theft--Any offense under the Texas Penal Code, Chapter 31.
- (7) Organized Crime—Any offense under the [.] Texas Penal Code, Chapter 71.
- (8) Any offense under Texas Health and Safety Code, Chapters 481, 482, or 483.
- (9) In addition:
  - (A) An attempt to commit a crime listed in this subsection;
  - (B) Aiding and abetting in the commission of a crime listed in this subsection; and
  - (C) Being an accessory before or after the fact to a crime listed in this subsection.
- (c) A felony conviction for an offense listed in subsection (b) of this section is disqualifying for ten (10) years from the date of the conviction.
- (d) A Class A or B misdemeanor conviction for an offense listed in subsection (b) of this section is disqualifying for five (5) years from the date of conviction.
- (e) Conviction for a felony or Class A offense that does not relate to the occupation for which registration is sought is disqualifying for five (5) years from the date of commission, pursuant to Texas Occupations Code, §53.021(a)(2).
- (f) Independently of whether the offense is otherwise described or listed in subsection (b) of this section, a conviction for an offense listed in Texas Code of Criminal Procedure, Article 42.12, §3g or Article 42A.054, or that is a sexually violent offense as defined by Texas Code of Criminal Procedure, Article 62.001, is permanently disqualifying subject to the requirements of Texas Occupations Code, Chapter 53.
- (g) Any unlisted offense that is substantially similar in elements to an offense listed in subsection (b) of this section is disqualifying in the same manner as the corresponding listed offense.

(h) A pending Class B misdemeanor charged by information for an offense listed in subsection (b) of this section is grounds for suspension.

(i) Any pending Class A misdemeanor charged by information or pending felony charged by indictment is grounds for suspension.

(j) In determining the fitness to perform the duties and discharge the responsibilities of the regulated occupation of an individual against whom disqualifying charges have been filed or who has been convicted of a disqualifying offense, the department may consider evidence of:

(1) The extent and nature of the individual's past criminal activity;

(2) The age of the individual when the crime was committed;

(3) The amount of time that has elapsed since the individual's last criminal activity;

(4) The conduct and work activity of the individual before and after the criminal activity;

(5) Evidence of the individual's rehabilitation or rehabilitative effort while incarcerated or after release;

(6) The date the individual will no longer be disqualified under the provisions of this section; and

(7) Any other evidence of the individual's fitness, including letters of recommendation from:

(A) Prosecutors or law enforcement and correctional officers who prosecuted, arrested, or had custodial responsibility for the individual; or

(B) The sheriff or chief of police in the community where the individual resides.

(k) In addition to the documentation listed in subsection (j) of this section, the applicant or registrant shall, in conjunction with any request for hearing on a criminal history based denial, suspension or revocation, furnish proof in the form required by the department that the individual has:

(1) Maintained a record of steady employment;

(2) Supported the individual's dependents;

(3) Maintained a record of good conduct; and

(4) Paid all outstanding court costs, supervision fees, fines and restitution ordered in any criminal case in which the individual has been charged or convicted.

(l) The information listed in subsection (j) and subsection (k) of this section must be submitted in conjunction with the request for hearing, following notification of the proposed action and prior to the deadline for submission of the request for hearing.

#### §12.4. Records.

(a) Records required under the Act or this chapter must be maintained and made available for inspection or copying for a period of two (2) years. Records may be maintained in digital form so long as a hard copy may be produced upon request of department personnel.

(b) In addition to any records otherwise required to be maintained under the Act or this chapter, licensees must specifically retain [The records detailed in this subsection must be maintained by all licensees for two (2) years, unless otherwise provided]:

(1) Copies of all [All] application materials submitted to the department or relied on in making any representation or affirmation in conjunction with the application process;

(2) Purchase, sale, and inventory records, including records reflecting the sources of all seeds and plants [of destruction];

(3) Shipping invoices, log books, records of duty status if applicable, delivery records and manifests reflecting the recipient's acknowledgment and establishing the chain of custody, relating to the transportation of:

(A) Low-THC cannabis and any cannabis sativa plants intended for use in the processing of low-THC cannabis;

(B) Raw materials used in or by-products created by the production or cultivation of low-THC cannabis; [or]

(C) Drug paraphernalia used in the production, cultivation or delivery of low-THC cannabis; or  
[.]

(D) Waste material resulting from cultivation, processing, or dispensing of low-THC cannabis.

(4) Security records, including building access and visitor logs, [and] video recordings, and transportation trip plans;

(5) The licensee's drug-free workplace policy;

(6) Records on all registered directors, managers, and employees, including a color photograph of the individual, a copy of the registration issued by the department, records reflecting the individual's position, assigned duties, and work schedule, and a copy of the company's drug-free workplace policy signed by the individual. These records must be maintained for two (2) years from the date employment is terminated.

(7) Records of any disposal or destruction of waste materials resulting from cultivating, processing, or dispensing low-THC cannabis;

(8) Records of any local or state regulatory inspections, including state or local fire marshal inspections; and

(9) Records of all tests conducted in compliance with §12.7 of this title (relating to Testing, Production, and Packaging).

§12.7. Testing, Production, and Packaging.

(a) Licensees must comply with all applicable provisions of the Texas Agriculture Code and the Texas Department of Agriculture's administrative rules, Title 4, Part 1.

(b) Representative samples of all [Licensees must test all] processed products must be tested for the levels of tetrahydrocannabinol and cannabidiol, and for residual solvents, pesticides, fungicides, fertilizers, mold, and heavy metals, in accordance with applicable provisions of the Texas Agriculture Code and Texas Department of Agriculture's administrative rules, Title 4, Part 1, and Code of Federal Regulations, Title 16, Part 1107.

[(c) All final packaging for patient consumption must be in child-resistant packaging designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by the most current version of the Code of Federal Regulations, Title 16, Part 1700 and Title 40, Part 157.2 and American Society for Testing and Materials (ASTM) D3475-15, Standard Classification of Child-Resistant Packages, ASTM International, West Conshohocken, PA, 2015.]

[(d) All final packaging labels must include:]

[(1) Physician's name;]

[(2) Patient's name;]

[(3) Dispensing organization's name, state license number, telephone number, and mailing address;]

[(4) Dosage prescribed and means of administration;]

[(5) Date the dispensing organization packaged the contents;]

[(6) Batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;]

[(7) Potency of the low-THC cannabis contained in the package, including the levels of tetrahydrocannabinol and cannabidiol;]

[(8) Statement that the product has been tested for contaminants with specific indications of all findings, and the date of testing in accordance with Code of Federal Regulations, Title 16, Part 1107; and]

[(9) Statement that the product is for medical use only and is intended for the exclusive use of the patient to whom it is prescribed. This statement should be in bold print.]

[(e) The dispensed product may contain no more than 0.5% by weight of tetrahydrocannabinols and not less than 10% by weight of cannabidiol.]

(c) Only pesticides of minimum risk exempted under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 USC §136, may be used on cannabis. The pesticide's active ingredients may only be those listed in 40 CFR §152.25(f)(1). The pesticide's inert ingredients may only be those that listed in 40 CFR §152.25(f)(2); commonly consumed food commodities, animal feed items, and edible fats and oils as provided in 40 CFR §180.950(a),(b) and (c); and chemical substances listed in 40 CFR §180.950(e). All pesticide ingredients (both active and inert) must be listed on the pesticide container's label. The active ingredient(s) must be listed by label display name and percentage by weight. Each inert ingredient must be listed by label display name. The product may not bear claims to control or mitigate organisms that pose a threat to human health, or insects or rodents carrying specific diseases. The name of the producer or the company for whom the product was produced and the company's contact information must be displayed prominently on the product label. The label cannot include any false or misleading statements. The label must comply with the Texas Department of Agriculture's administrative rule, 4 TAC §7.11, relating to Label Requirements.

(d) All facilities must be inspected and approved for their use by a local fire code official, or by the state fire marshal or local designee of the state fire marshal, and must meet any required fire, safety, and building code requirements specified in:

(1) National Fire Protection Association (NFPA) standards;

(2) International Building Code (IBC);

(3) International Fire Code (IFC);

(4) Texas Department of Insurance administrative rules, 28 TAC Chapter 34, concerning State Fire Marshal; and

(5) Other applicable standards including following all applicable fire, safety, and building codes in processing and the handling and storage of the solvent or gas.

(e) Licensees must provide certification by a Texas licensed professional engineer that the extraction system to be used to produce low-THC cannabis products was commercially manufactured, safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, such as:

(1) The American Society of Mechanical Engineers (ASME);

(2) American National Standards Institute (ANSI);

(3) Underwriters Laboratories (UL); or

(4) The American Society for Testing and Materials (ASTM).

(f) The extraction process must be continuously staffed during operations by a registered employee trained in the extraction process, the transfer of LP-gas where applicable, and all emergency procedures. All staff training records shall be maintained on-site and made available upon request by the department or local law enforcement or regulatory official.

(g) The installation, operation, repair and maintenance of electrical systems, devices, and components shall conform to the National Electrical Code, NFPA 70 as adopted by the Texas Department of Licensing and Regulation. All electrical components within the extraction room shall be interlocked with the hazardous exhaust system and when provided, the gas detection system. When the hazardous exhaust system is not operational, or the gas detection system is activated, light switches and electrical outlets shall be disabled while leaving lights on that are necessary for evacuation. The electrical systems shall include:

(1) Extraction room lighting;

(2) Extraction room ventilation system;

(3) Solvent gas detection system;

(4) Emergency alarm systems;

(5) Automatic fire extinguishing systems;

(6) Vent failure alarm system; and

(7) Emergency power backup system.

(h) For extraction processes utilizing gaseous hydrocarbon-based solvents, a continuous gas detection system shall be provided. The gas detection threshold shall be no greater than 10% of the LEL/LFL limit of the materials.

(i) Signs shall be posted at the entrance to each production area using or storing carbon dioxide, indicating the hazard. Signs shall be durable and permanent in nature and not less than 7 inches wide by 10 inches tall. Signs shall bear the "skull and crossbones" emblem with the warning "DANGER! POTENTIAL OXYGEN DEFICIENT ATMOSPHERE". NFPA 704 signage shall be provided at the building main entry and the rooms where the carbon dioxide is used and stored. The main entrance to the facility and any door to a room where storage, transfer or use of hazardous materials is conducted shall be appropriately posted with markings in accordance with

NFPA 704, Standard System for the Identification of the Hazards of Materials for Emergency Response.

(j) Mechanical ventilation within an extraction or processing facility shall be in accordance with the applicable local ordinances or the appropriate NFPA standard as adopted by the State Fire Marshal's Office if no applicable local ordinance exists, and shall have:

(1) Mechanical ventilation in the room or area of rate of not less than 1 cubic foot per minute per square foot;

(2) Exhaust system intake from a point within 12 inches of the floor; and

(3) Ventilation operating at a negative pressure in relation to the surrounding area.

(k) Any liquid extraction process using flammable and combustible liquids in which the liquid is boiled, distilled, or evaporated must operate in compliance with this section and NFPA 30 as adopted by the State Fire Marshal's Office.

(l) Any processing equipment using a flammable or combustible vapor or liquid must meet the requirements of NFPA 30 and NRPA 70. Such equipment shall be located within a hazardous exhaust fume hood, rated for exhausting flammable vapors. Electrical equipment used within the hazardous exhaust fume hood shall be rated for use in flammable atmospheres. Heating of flammable or combustible liquids over an open flame is prohibited, with the exception that the use of a heating element not rated for flammable atmospheres may be used where documentation from the manufacturer or a nationally recognized testing laboratory indicates it is rated for heating of flammable liquids.

(m) Product extraction processes may use only potable water in compliance with Code of Federal Regulations, Title 40, Part 141.

(n) All regulated premises shall be located at least 1000 feet from any private or public school or day care center that existed prior to the date of initial license application, measured from the closest points on the respective property lines.

(o) All final packaging for patient consumption must be in child-resistant packaging designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by the most current version of the Code of Federal Regulations, Title 16, Part 1700 and Title 40, Part 157.2 and American Society for Testing and Materials (ASTM) D3475-15, Standard Classification of Child-Resistant Packages, ASTM International, West Conshohocken, PA, 2015.

(p) All final packaging labels must include:

(1) Physician's name;

(2) Patient's name;

(3) Dispensing organization's name, state license number, telephone number, and mailing address;

(4) Dosage prescribed and means of administration;

(5) Date the dispensing organization packaged the contents;

(6) Batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;

(7) Potency of the low-THC cannabis product contained in the package, including the levels of tetrahydrocannabinol and cannabidiol;

(8) Statement that the product has been tested for contaminants with specific indications of all findings, and the date of testing in accordance with Code of Federal Regulations, Title 16, Part 1107; and

(9) Statement that the product is for medical use only and is intended for the exclusive use of the patient to whom it is prescribed. This statement should be in bold print.

(q) The dispensed product may contain no more than 0.5% by weight of tetrahydrocannabinols and not less than 10% by weight of cannabidiol.

(r) The storage, transfer, and use of LP- Gas shall conform to the regulations of the Texas Railroad Commission, including but not limited to NFPA 58, LP Gas Code (as amended) and the adopted standards of the State Fire Marshal's Office.

(s) The storage, use and handling of liquid carbon dioxide shall be in accordance with Chapter 13 of NFPA 55.

#### §12.8. Inventory Control System.

(a) A licensed dispensing organization shall use a perpetual inventory control system that identifies and tracks the licensee's stock of low-THC cannabis from the time the seeds are acquired or it is propagated from seed or cutting, to the time it is delivered to either another licensee or [a qualifying] patient or legal guardian.

(b) The inventory control system shall be capable of tracking low-THC cannabis from a [qualified] patient back to the source of the low-THC cannabis in the event of a serious adverse event.

(c) The inventory control system shall be designed to promptly identify a discrepancy and interact with the department's centralized registry system.

(d) Upon receipt of raw material for cultivation, a licensee shall record in the inventory control system:

(1) The source and the date delivered; and

(2) The number of clones or seeds delivered or the weight of the seeds for each variety in the shipment.

(e) For each plant, including any clippings to be used for propagation, a licensee shall:

(1) Create a unique identifier;

(2) Assign a batch number;

(3) Enter appropriate plant identifying information into the inventory control system;

(4) Create an indelible and tamper resistant tag made of temperature and moisture resistance material, with a unique identifier and batch number;

(5) Securely attach the tag to a container in which a plant is grown until a plant is large enough to securely hold a tag;

(f) Upon curing or drying of each batch, a licensee shall weigh the batch and enter the weight into the [low-THC cannabis to update] inventory control system database [for the batch].

(g) At least monthly, a licensee shall conduct a physical inventory of the stock and compare the physical inventory of stock with inventory control system data.

(h) If a licensee discerns a discrepancy between the inventory of stock and inventory control system data outside of normal weight loss due to moisture loss and handling, a licensee shall begin [commence] an audit of the discrepancy.

(i) Within fifteen (15) business days of discovering a discrepancy, the licensee shall:

(1) Complete an audit;

(2) Amend the licensee's standard operating procedures, if necessary; and

(3) Send an audit report to the department.

(j) If a licensee finds evidence of theft or diversion, the licensee shall immediately report the theft or diversion to the department.

§12.9. Sanitation; Waste Disposal.

(a) Licensees must maintain regulated premises in a clean and sanitary condition, and shall take all reasonable measures to ensure:

(1) Litter and waste are routinely removed and waste disposal systems are routinely inspected in accordance with applicable local, state, or federal law, rule, regulation or ordinance;

(2) Fixtures, floors, walls, ceilings, buildings or other facilities are kept in good repair;

(3) Regulated premises are adequately screened and otherwise protected against the entry of pests;

(4) Refuse disposal is conducted in a manner to minimize the development of odor and the potential for breeding of pests;

(5) Contact surfaces, including utensils and equipment used for the cultivation, drying, trimming, or storage of product, are cleaned and sanitized in a manner to protect against contamination;

(6) Potentially toxic chemicals used within the cultivation facility are identified, stored, and disposed of in a manner to protect against contamination of the product, in compliance with all applicable local, state, or federal laws, rules, regulations or ordinances;

(7) Storage and transportation of product is under conditions that protect against physical, chemical, and microbial contamination;

(8) Safes, vaults, and storage rooms are in good working order, with climate control systems sufficient to prevent spoilage;

(9) Processing site is free of contamination and suitable for the safe and sanitary preparation of the product, including ensuring all equipment, counters and surfaces used for processing are food-grade and nonreactive with any solvent being used, with easily cleanable surface areas constructed in a manner to reduce the potential for development of mold or fungus;

(10) Hand-washing facilities provide effective hand-cleaning and sanitizing materials, with sanitary towel service or hand drying devices, and hot and cold running water;

(11) All persons working in direct contact with product conform to hygienic practices while on duty, including but not limited to:

(A) Maintaining adequate personal cleanliness, including washing hands thoroughly before handling product and as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks;

(B) Refraining from direct contact with product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected;

(C) Keeping fingernails trimmed and filed so that the edges and surfaces are cleanable;

(D) Unless wearing intact gloves in good repair, having no fingernail polish or artificial fingernails on the employee's fingernails;

(E) Wearing clean clothing appropriate to assigned tasks or protective apparel such as coats, aprons, gowns, or gloves to prevent contamination; and

(F) Reporting to the employer's director or manager any health condition experienced by the employee that may adversely affect the safety or quality of product with which the employee may come into contact;

(12) Prohibiting any employee with a health condition that may adversely affect the safety or quality of the product from having direct contact with any product or equipment or materials for processing low-THC cannabis, or from performing any task that reasonably might contaminate or adversely affect any product.

(b) Destruction and disposal of waste materials resulting from the cultivation or processing of low-THC cannabis must be conducted in compliance with applicable state and local laws and regulations, and Code of Federal Regulations, Title 21, Part 1317, Subpart C. Any waste materials containing low-THC cannabis or raw materials used in or by-products created by the production or cultivation of low-THC cannabis must be rendered irretrievable, as defined in Code of Federal Regulations, Title 21, Part 1300. Waste water generated during production and processing must be disposed of in compliance with applicable state and local laws.

(c) Licensees are responsible for determining whether specific waste materials or waste water constitute hazardous waste under applicable federal or state regulations and for ensuring disposal of any such waste complies with applicable disposal regulations.

(d) All waste materials must be stored on the licensee's premises prior to destruction and disposal.