

**Texas Department of Public Safety
Regulatory Services Division**

**Compassionate Use / Low-THC Cannabis Program Administrative Rules
Effective March 15, 2017**

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Subchapter A General Provisions

§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 involved in decisions governing the operation or daily functions of the licensed dispensing organization, and any owner, partner, or shareholder of the business with an ownership interest that exceeds 10 percent.
- (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 cultivated, handled, transported, processed, or dispensed.
- (13) SOAH--State Office of Administrative Hearings.

§12.2. Requirements and Standards.

- (a) A licensee may only perform regulated functions at a department approved location. 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 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, inventory and destruction records, or other records required under the Act or this chapter, and the compliance with any lawfully issued subpoena.
- (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 patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code, or the patient's legal guardian.
- (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 regulated under the Act for the licensee(s) 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 notified by the registrant 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 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 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, noise, and odor or other nuisances. This subsection does not require compliance with a regulation that conflicts with the Act or this chapter.
- (n) 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.
- (o) 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 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 two (2) years 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) Only low-THC cannabis may be dispensed or sold. By-products must be destroyed.
- (x) 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:
 - (1) Copies of 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;
 - (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;
 - (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, 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).

§12.5. Address on File.

- (a) All licensees, registrants, or applicants shall at all times maintain on file with the department a current electronic mail address, physical mailing address, facsimile number, and the physical address of each location at which low-THC cannabis is cultivated, processed, or dispensed.
- (b) All licensees or registrants shall notify the department of any change to their addresses on file in the manner provided on the department's website prior to the effective date of the change of address.

§12.6. Notice.

- (a) The department is entitled to rely on the physical mailing address, the facsimile number, and the electronic mail address currently on file for all purposes relating to notification. The failure to maintain current addresses with the department is not a defense to any action based on the licensee's, registrant's, or applicant's failure to respond.
- (b) Service of notice is complete and receipt is presumed upon the date the notice is sent, if sent before 5:00 p.m. by facsimile transmission or electronic mail, or three (3) days following the date sent, if notice is sent by regular United States mail or certified mail, return receipt requested.
- (c) Unless otherwise specified by the Act, notifications by the department may be by facsimile transmission, electronic mail, regular U.S. mail, certified mail, return receipt requested, or hand-delivery.

§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 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) 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 (5) 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 it is propagated from seed or cutting, to the time it is delivered to either another licensee or patient or legal guardian.
- (b) The inventory control system shall be capable of tracking low-THC cannabis from a 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 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 inventory control system database.
- (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 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 report the theft or diversion to the department within two (2) days of the discovery of the theft or diversion.

§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.

Subchapter B Application and Renewal

§12.11. Application for License.

- (a) Application for license as a dispensing organization may only be made in the manner determined by the department.
- (b) A complete application must include the items detailed in this subsection, in a manner determined by the department:
 - (1) Proof of ownership and current status in the manner required by the department, including but not limited to a current Certificate of Existence or Certificate of Authority from the Texas Office of the Secretary of State and a Certificate of Good Standing from the Texas Comptroller of Public Accounts;
 - (2) All application fees required under §12.14 of this title (relating to Application and Licensing Fees and Method of Payment);
 - (3) Names, dates of birth, addresses, and all other information required by the department necessary to verify the identity of all directors, managers, and employees of the applicant;
 - (4) Criminal history disclosure of all convictions and deferred adjudications for each individual listed on the application as directors, managers, and employees of the dispensing organization;
 - (5) Complete registration applications for all directors, managers and employees submitted in the manner approved by the department and in compliance with §12.12 of this title (relating to Application for Registration);
 - (6) Proof of commercial general liability insurance coverage against claims of liability for damage to property of third parties and for personal injuries to third parties, including bodily injury, property damage, and product liability, with limits of:
 - (A) \$1,000,000 each occurrence;
 - (B) \$2,000,000 General Aggregate limit; and
 - (C) \$1,000,000 Product Liability.
 - (7) Evidence of the qualifications detailed in this paragraph as determined at the time of the required onsite inspection, in the manner determined by the department:
 - (A) The technical and technological ability to cultivate, process, and/or dispense low-THC cannabis, evidenced by experience in the areas of:

- (i) Cultivation, analytical organic chemistry and micro-biology; and analytical laboratory methods; and
 - (ii) Patient education and interaction, and the handling of confidential information including familiarity with the requirements of the Health Insurance Portability and Accountability Act (HIPAA).
- (B) The ability to secure the premises, resources, and employees necessary to operate as a dispensing organization, evidenced by:
- (i) Descriptions of all properties applicant proposes to utilize to cultivate, process, and dispense low-THC cannabis, including ownership information for the properties;
 - (ii) Descriptions of the methods proposed for the cultivation, processing, and dispensing of low-THC cannabis;
 - (iii) Descriptions of the types and locations of worker safety equipment and plans and procedures for complying with federal Occupational Safety and Health Administration (OSHA) regulations for workplace safety;
 - (iv) A list of current and proposed staff, including, position, duties and responsibilities, and an organizational chart illustrating the supervisory structure of the dispensing organization;
 - (v) Description of the applicant's proposed testing laboratory, and description of the proposed testing protocols and methods;
 - (vi) A proposal establishing the ability to secure premises reasonably located to allow patient access through existing infrastructure; and
 - (vii) Department approved acknowledgments executed by the applicant's directors, managers and employees indicating familiarity with the federal laws governing marijuana and its interstate transportation.
- (C) The ability to maintain accountability of all raw materials, finished products, and any by-products to prevent diversion or unlawful access to or possession of these substances, evidenced by:
- (i) Floor plan of each facility or proposed floor plans for proposed facilities, including:
 - (I) Locking options for all means of ingress and egress consistent with life safety requirements;
 - (II) Alarm systems;
 - (III) Video surveillance;

- (IV) Name, layout and function of each room; and
 - (V) Storage, including safes and vaults.
 - (ii) Diversion prevention procedures;
 - (iii) Emergency management plan;
 - (iv) System for tracking source plant material throughout cultivation, processing, and dispensing;
 - (v) Inventory control system as required by §12.8 of this title (relating to Inventory Control System);
 - (vi) Policies and procedures for recordkeeping;
 - (vii) Electronic vehicle tracking systems;
 - (viii) Vehicle security systems;
 - (ix) Methods of screening and monitoring employees;
 - (x) Employee qualifications and experience with chain of custody or other tracking mechanisms;
 - (xi) Waste disposal plan;
 - (xii) Recall procedures for any product that has a reasonable probability of causing adverse health consequences based on a testing result, patient reaction, or other reason; and
 - (xiii) Access to specialized resources or expertise regarding data collection, security, and tracking.
- (D) Infrastructure reasonably located to dispense low-THC cannabis to registered patients, evidenced by:
- (i) Map showing the location of the applicant's proposed dispensing facilities with streets; property lines; buildings; parking areas; outdoor areas, if applicable; fences; security features; fire hydrants, if applicable; and access to water and sanitation systems;
 - (ii) Floor plan of the actual or proposed building or buildings where dispensing activities will occur showing areas designed to protect patient privacy and areas designed for retail sales, with proposed hours of operation;
 - (iii) HIPAA compliant computer network utilized by all facilities;
 - (iv) Identifying descriptions of any vehicles to be used to transport product; and

- (v) Description of all communication systems.
- (E) The financial ability to maintain operations for two (2) years from the date of application, evidenced by:
- (i) Applicant's business organization, and corporate structure if applicable;
 - (ii) List of all owners of any non-corporate applicant, or all shareholders of a corporate applicant;
 - (iii) All individuals and entities with control over the applicant;
 - (iv) Projected two (2) year budget; and
 - (v) Description of available assets sufficient to support the dispensing organization activities.
- (c) Subsequent to the submission of all information and documentation required by subsection (b)(1) - (6) of this section and the conditional approval of the application, the department will conduct an onsite inspection to confirm applicant's compliance with the requirements of subsection (b)(7) of this section and of this chapter generally. The applicant must pass the inspection prior to licensure. Failure to pass the inspection will result in notification of the basis for the failure. Failure to address the basis for the failure within sixty (60) days of notice may result in the denial of the application, pursuant to §12.15 of this title (relating to Denial of Application for License). Upon request of the applicant, the department may extend the period to address the basis for the failure for one (1) additional thirty (30) day period.
- (d) Failure of an applicant to submit all information and documentation required by subsection (b)(1) - (6) of this section will result in notification of the deficiency. Applicant will have ninety (90) days from the date of notice to address the deficiency. Upon request of the applicant, the department may extend the period to address the deficiency for one (1) additional ninety (90) day period. If an applicant fails to provide all required application materials, or fails to respond to a request by the department for additional information necessary to process the application, the application will be terminated. Following the termination of an application, a new application, including a new application fee, must be submitted.

§12.12. Application for Registration.

- (a) In conjunction with the dispensing organization's application for license, or prior to employment with a currently licensed dispensing organization, directors, managers, and employees must submit:
- (1) Identifiers, including the individual's full name, date of birth, telephone number, electronic mail address, residential address, and driver license or state-issued identification number; and
 - (2) Fingerprints submitted in the manner approved by the department.
- (b) If the applicant does not have a digital photograph on file with the department or the department is unable to access the photograph on file, the registration card will be issued without a photograph. When presenting such a card to a peace officer or to a representative of the

department, the registrant shall also present a valid government issued identification card or driver license.

- (c) Failure of an applicant to comply with the requirements of this section will result in notification of the deficiency. Applicant will have ninety (90) days from the date of notice to address the deficiency. Upon request of the applicant, the department may extend the period to address the deficiency for one additional ninety (90) day period. If an applicant fails to provide all required application materials, or fails to respond to a request by the department for additional information necessary to process the application, the application will be terminated. Following the termination of an application, a new application, including a new application fee, must be submitted.

§12.13. Renewal.

- (a) A license or registration may be renewed at any time during the six (6) months prior to expiration.
- (b) A renewal applicant must pass department inspection prior to approval of the application. This requirement is satisfied by an inspection within ninety (90) days prior to the submission of the renewal application.
- (c) An expired license or registration may be renewed for up to six (6) months after the expiration date. If the license has been expired for more than six (6) months, the former license holder must submit an original license application to receive a license in the future.

§12.14. Application and Licensing Fees and Method of Payment.

- (a) The application fee for a dispensing organization license is \$7,356. The license fee for a dispensing organization is \$488,520 for a two (2) year period.
- (b) The fee for the biennial renewal of the dispensing organization license is \$318,511.
- (c) The registration fee is \$530 for both the original registration and renewals.
- (d) Payment of all fees must be made electronically in the manner determined by the department.
- (e) If payment is dishonored or reversed prior to issuance of the license or registration, the application will be rejected as incomplete. If the license or registration has been issued prior to the payment being dishonored or reversed, revocation proceedings will be initiated pursuant to §12.23 of this title (relating to Revocation). The department may dismiss a pending revocation proceeding upon receipt of payment of the full amount due, including any additional processing fees.

§12.15. Denial of Application for License.

- (a) The department may deny the application for a license as a dispensing organization if the applicant fails to pass the initial review of the application materials or the onsite inspection, based on the failure to satisfy the requirements reflected in subsection (b)(7) of §12.11 of this title (relating to Application for License), and has either failed to address the basis for the failure within sixty (60) days of notice of the failure, or has failed to request an additional thirty (30) days to address the basis for the failure.

- (b) The department may deny the application for a license if the applicant is found to have violated any provision of the Act or this chapter, or §§481.120, 481.121, 481.122, or 481.125 of the Texas Health and Safety Code prior to licensure or renewal.
- (c) The department may also deny the application for a license from an otherwise qualified applicant if the department determines issuance of the license is not necessary to ensure reasonable statewide access to, and the availability of low-THC cannabis for patients registered in the compassionate-use registry and for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.
- (d) Following the notice of denial the applicant will be provided thirty (30) days to request a hearing by submitting a request through the department's website.

§12.16. Denial of Application for Registration.

- (a) The department may deny the application for registration of a director, manager, or employee of a dispensing organization if the applicant is disqualified pursuant to §12.3 of this title (relating to Criminal History Disqualifiers). The applicant may request a hearing by submitting a request through the department's website within thirty (30) days of the date of the denial notice.

Subchapter C Compliance and Enforcement

§12.21. Inspections.

- (a) Submission of an application for a license as a dispensing organization constitutes permission for entry by the department to the regulated premises of the dispensing organization at any time during regular business hours.
- (b) While conducting an inspection or engaging in activity reasonably related to the inspection, the department may be assisted by a peace officer, a representative of the State Fire Marshal's Office or another appropriate state or local regulatory agency.
- (c) Within thirty (30) calendar days of the date of receipt of the written notice of violation, the dispensing organization shall provide the department with notification of all corrective actions taken and the dates of the corrections.
- (d) Onsite inspections may include but are not limited to review of:
 - (1) All requirements provided in §12.11(b) of this title (relating to Application for License);
 - (2) Security equipment and protocols as provided in Subchapter D of this title (relating to Security);
 - (3) Records as provided in §12.4 of this title (relating to Records).
- (e) Failure to cooperate with an inspection by department or other authorized personnel may result in suspension or revocation of the individual's registration and the license of the dispensing organization.

§12.22. Suspension.

- (a) The department may initiate suspension proceedings against the license of a dispensing organization if the licensee or its registrant:
 - (1) Willfully or knowingly submits false, inaccurate, or incomplete information to the department or records such information on any records required to be maintained under this chapter;
 - (2) Fails to maintain the records required under this chapter; or
 - (3) Violates any provision of the Act, of this chapter, or §§481.120, 481.121, 481.122, or 481.125 of the Texas Health and Safety Code.
- (b) For the first violation of subsection (a) of this section, the license may be suspended for a period not to exceed thirty (30) days.
- (c) For multiple first time violations, or for a second violation of subsection (a) of this section occurring within two (2) years of an earlier violation for which a final order has been issued, the license may be suspended for a period not to exceed ninety (90) days.
- (d) For multiple, repetitive violations, or for a third violation of subsection (a) of this section occurring within two (2) years of two (2) earlier violations for which final orders have been issued, the license may be suspended for a period not to exceed one hundred eighty (180) days.
- (e) Upon receipt of a notice of suspension under this section, the licensee will be provided with thirty (30) days to address the violation or request a hearing before SOAH. The failure to timely appeal the proposed action will result in the issuance of a final order.
- (f) Registrants may be suspended if charged by misdemeanor information or felony indictment with a disqualifying offense as provided in §12.3 of this title (relating to Criminal History Disqualifiers).

§12.23. Revocation.

- (a) The department may revoke a license or registration if the licensee or registrant:
 - (1) Is found to have performed a regulated function prior to issuance of the license or registration;
 - (2) Misrepresents a material fact in any application to the department or any other information filed pursuant to the Act or this chapter;
 - (3) Prepares or submits to the department false, incorrect, incomplete or misleading forms or reports on multiple occasions;
 - (4) Performs a regulated function while suspended;
 - (5) Exhibits a pattern of misconduct evidenced by previous violations for which previous suspensions have been inadequate to affect compliance;

- (6) Is convicted of a disqualifying felony or misdemeanor offense pursuant to §12.3 of this title (relating to Criminal History Disqualifiers);
 - (7) Violates §§481.120, 481.121, 481.122, or 481.125 of the Texas Health and Safety Code; or
 - (8) Submits to the department a payment that is dishonored, reversed, or otherwise insufficient or invalid.
- (b) Following notification of the violation, the licensee will be provided with thirty (30) days to address the violation or request a hearing by submitting the request electronically through the department's website or as otherwise determined by the department. If a hearing is requested, the department will schedule a hearing before SOAH.
 - (c) Except as provided in subsection (b) of this section, an individual whose certificate of registration has been revoked may not be relicensed or reregistered earlier than two (2) years from the date of revocation.
 - (d) An individual whose registration has been revoked for a dishonored or reversed payment, as provided under subsection (a)(8) of this section may reapply at any time. Approval of the application is contingent upon receipt of payment of the full amount due, including any additional processing fees resulting from the prior dishonored or reversed payment. The department may dismiss a pending revocation proceeding based on a dishonored or reversed payment upon receipt of payment of the full amount due, including any additional processing fees resulting from the prior dishonored or reversed payment.
 - (e) Other than as provided in subsection (d) of this section, an individual whose license or registration has been revoked must follow the applicable procedures pursuant to §12.11 or §12.12 of this title (relating to Application for License and Application for Registration, respectively) for new applications.

§12.24. Default Judgments.

Following adequate notice of a hearing on a contested case before SOAH, failure of the respondent to appear at the time of hearing shall entitle the department to request from the administrative law judge an order dismissing the case from the SOAH docket and to informally dispose of the case on a default basis.

§12.25. Hearing Costs.

- (a) In cases brought before SOAH, in the event the respondent is adjudicated as being in violation of the Act or this chapter after a trial on the merits, the department has authority to assess the actual costs of the administrative hearing in addition to the penalty imposed. Such costs include, but are not limited to, investigative costs, witness fees, deposition expenses, travel expenses of witnesses, transcription expenses, or any other costs that are necessary for the preparation of the department's case.
- (b) The costs of transcriptions and preparation of the record for appeal shall be paid by the respondent.

Subchapter D Security

§12.31. Security of Facilities.

- (a) A licensee or applicant for licensure must maintain effective controls and procedures in order to prevent unauthorized access, theft, or diversion of the low-THC cannabis and any derivative products. The standards provided in this subchapter are minimum standards only.
- (b) During the regular course of business activities, and except as provided by subsection (d) of this section, a licensee may not allow access to the facility's cultivation, processing, or product storage areas by unauthorized individuals or to the public. All cultivation of low-THC cannabis shall take place in an enclosed, secured building, or an enclosure within a building that provides reasonably adequate protection against the diversion of low-THC cannabis or raw materials used in or by-products created by the production or cultivation of low-THC cannabis; limit access to each area to the minimum number of individuals or employees necessary for the licensee's activities; and designate an individual or a limited number of individuals with responsibility for each area where a controlled item is cultivated, processed, dispensed, produced, or stored; and authority to enter or control entry into the area. Access to the enclosed, locked area is limited to a licensee, director, manager or registered employee when acting in his or her official capacity.
- (c) Access to the licensee's cultivation, processing, or product storage areas by authorized employees shall at a minimum be restricted by a physical barrier with a mechanical locking device compliant with life safety requirements that must be kept closed and locked at all times when not immediately being used to enter or exit the area. These areas shall be clearly and conspicuously marked at all access points with signage indicating access is restricted to individuals registered with the Texas Department of Public Safety under Chapter 487 of the Texas Health and Safety Code, in contrasting block letters at least one inch in height.
- (d) When unregistered individuals, whether employees or contractors, business guests or visitors, or maintenance or other service providers not regulated under the Act, are to be present in or are to pass through regulated premises, the unregistered individuals must be continuously escorted by a registrant. Unregistered individuals must be provided a visitor's badge reflecting the individual's name and the date of issuance. All ingress and egress by unregistered individuals must be recorded in a daily log. The log must include the full name of each unregistered individual entering the regulated premises, the time of arrival, the time of departure, and the purpose of the visit. The requirements of this subsection do not apply to representatives of the department or other law enforcement agencies of this state who tour the facility as part of their official duties.
- (e) Licensees must have an alarm system capable of continuously monitoring the regulated premises for fire and intrusion by means of camera recording, door switches, motion sensors, and fire and smoke detectors. The system must have the capability of immediately alerting local law enforcement of a fire at any time, of a security breach during non-business hours, and of being manually activated by staff during business hours. The camera monitoring system must be capable of recording at least 90 days of footage to an external hard drive at a minimum resolution of 720 x 350, with camera coverage of all regulated areas, including all ingress or egress areas, and the building exterior. Point of sale areas, if applicable, must have a camera placed in a manner to provide visual identification of any patient or legal guardian seeking to fill a prescription for low-THC cannabis. Exterior lighting must be sufficient to support camera monitoring. The system must comply with local city or county alarm

permitting requirements. The system must be capable of continuous function upon total power loss for a minimum period of five (5) minutes.

- (f) Access to the licensee's cultivation, processing, or product storage areas must be through a metal security door on a metal frame with hinges that are protected from ingress. The metal door must have secure locking capability. The door, door frame, and locking mechanism must be compliant with life safety requirements. If the door utilizes magnetic locks, the lock must work independently without exterior power. Post-cultivation low-THC cannabis products must be stored in a locking safe or metal locking container, in compliance with Title 21 Code of Federal Regulations, §1301.72.
- (g) The licensee's cultivation, processing, production, or raw material storage areas should have no windows unless the windows are shatter resistant or burglar proof, or are reinforced with metal bars or grates to prevent entry.
- (h) In the event the licensee's facility shares space, or has an adjacent building, the facility must ensure no mutual access points exist, including ceiling or roof areas which would enable unauthorized access from the adjacent structure.
- (i) Final low-THC cannabis products and raw materials, including plants in any stages of growth, may not be visible from the exterior of the building during non-business hours.

§12.32. Security of Vehicles.

- (a) Any vehicle used by a dispensing organization for the transportation of low-THC cannabis must have a vehicle security system and a securely attached and locked container within the vehicle. It is the responsibility of the licensee to ensure that only authorized registered employees have access to the locked secure container within the vehicle.
- (b) Prior to transportation of any product, licensee shall complete a trip plan that includes:
 - (1) The name of the registrant responsible for the transportation;
 - (2) The date and start time of the trip;
 - (3) The anticipated route of transportation and destination; and
 - (4) A detailed invoice or log of the specific type of product and amount to be transported.
- (c) Promptly following transportation, the licensee shall enter the end time of the trip and any changes to the trip plan, including any changes to the amount of product delivered to the location.

§12.33. Response to Security Breach.

- (a) The licensee must immediately report any unauthorized intrusion or other security breach of the regulated premises to both the local law enforcement agency with primary response jurisdiction and within twenty four (24) hours to the department.
- (b) Following any security breach the licensee shall review existing security procedures for any deficiencies that may have contributed to the breach. The licensee shall remedy the deficiency and report the remedial measures to the department.

- (c) The licensee must rekey or change the combinations of any locks opened in the breach, and change any passwords that may have been used in the breach.

Subchapter E Compassionate Use Registry

§12.41. Access to Compassionate-Use Registry.

- (a) Qualified physicians registered as prescribers of low-THC cannabis under Texas Occupations Code, Chapter 169 may access the Compassionate-Use Registry using the department's secure web portal.
- (b) Dispensing organizations and law enforcement agencies may request access to the Compassionate-Use Registry for purposes of the Act and this chapter, including verifying whether a patient is one for whom low-THC cannabis is prescribed and whether the patient's prescriptions have been filled.

§12.42. Verification of Patient Prescription.

- (a) Before dispensing any low-THC cannabis to a registered patient or the patient's legal guardian, the dispensing organization must verify the identity of the patient or guardian, verify the guardian's status, if applicable, and otherwise comply with the requirements of §487.107 of the Act.
- (b) Upon dispensing the low-THC cannabis, the dispensing organization shall immediately enter into the registry the form and quantity of low-THC cannabis dispensed, the amount charged for the low-THC cannabis dispensed, and the date and time of dispensation.

§12.43. Prescriber Registration

- (a) In addition to the requirements of Texas Occupations Code Section 169.004, for purposes of identification the physician's registration must include the patient's address, the last four digits of the patient's Social Security Number, and if applicable, the name of the patient's legal guardian.
- (b) Physicians registered as prescribers of low-THC cannabis under Texas Occupations Code Chapter 169 must immediately inform the department of any change to their qualifications to prescribe under Section 169.002.

§12.44. Prescriptions

Prescriptions for low-THC cannabis must be submitted electronically to the Compassionate Use Registry in compliance with Texas Occupations Code Section 169.003, and may be confirmed and dispensed based on the electronic prescription record in accordance with Section 487.107 of the Act.

Subchapter F Special Conditions for Military Service Members and Spouses

§12.51. Definitions

For purposes of this subchapter, the terms "military service member", "military veteran", and "military spouse" have the meanings provided in Texas Occupations Code Section 55.001.

§12.52. Exemption from Penalty for Failure to Renew in Timely Manner

An individual who holds a registration or license issued under the Act is exempt from any increased fee or other penalty for failing to renew the license or registration in a timely manner if the individual establishes to the satisfaction of the department the individual failed to renew the license or registration in a timely manner because the individual was serving as a military service member.

§12.53. Extension of License Renewal Deadlines for Military Members

A military service member who holds a registration or license issued under the Act is entitled to two (2) years of additional time to complete any requirement related to the renewal of the license.

§12.54. Alternative Licensing for Military Service Members, Military Veterans, and Military Spouses

- (a) An individual who is a military service member, military veteran, or military spouse may apply for a license under this section if the individual:
 - (1) Holds a current license issued by another jurisdiction with licensing requirements substantially equivalent to the Act's requirements for the license; or
 - (2) Held a license in this state within the five (5) years preceding the date of application.
- (b) The department may accept alternative demonstrations of professional competence in lieu of existing experience, training, or educational requirements.

§12.55. Credit for Military Experience and Training

- (a) Verified military service, training, or education that relates to the registration or license for which a military service member or military veteran has applied will be credited toward the respective experience or training requirements.
- (b) This section does not apply to an applicant who:
 - (1) Holds a restricted license issued by another jurisdiction; or
 - (2) Is ineligible for the registration or license under the Act or this chapter, based on a disqualifying criminal history.

Subchapter G Production Limits

§12.61. Production Limits.

- (a) This subchapter limits the amount of annual statewide production by licensees to the estimated demand as calculated under this subchapter but shall not be construed as adopting a standard of care for treatment involving the product. The intent of this subchapter reflects legislative intent to serve a narrow population of patients living with intractable epilepsy, as defined under Occupations Code, Chapter 169. The subchapter includes a provision allowing the department to increase the established production limit. This provision shall be executed if ever necessary to prevent the subchapter from ever being the cause of a patient legally prescribed the product under Occupations Code, Chapter 169, from being unable to access his or her full prescription from a licensee.

- (b) On the first of every September or in accordance with subsection (i) of this section, the Department of State Health Services shall provide a report to the department with:
 - (1) a current estimate of people living with intractable epilepsy, as defined by Occupations Code, Chapter 169, in Texas; and
 - (2) the most current scientifically accepted dosage of product used to treat an average individual living with intractable epilepsy for one (1) year.
- (c) Any information reported under subsection (b) of this section:
 - (1) may be extrapolated from the number of beneficiaries receiving state public assistance treating individuals with intractable epilepsy;
 - (2) is strictly for the purpose of estimating a limit on production under this chapter; and
 - (3) shall not be construed as the Department of State Health Services adopting a standard of care for treating intractable epilepsy.
- (d) Upon receipt of the report required under subsection (b), the department shall determine the maximum amount of product allowed to be produced statewide, which shall be limited to:
 - (1) an amount required to treat one third of the population described in subsection (b)(1) of this section with each individual receiving the dosage determined by subsection (b)(2) of this section, if prior to September 1, 2018; or
 - (2) the amount of product demand from the previous twelve (12) month period grown by a percent equal to the growth over the same previous twelve (12) month period in the population described by subsection (b)(1), if after September 1, 2018.
- (e) The department shall determine a maximum amount of cannabis sativa plants needed to produce the amount of product described in subsection (d) and subsection (j) of this section, if applicable.
- (f) Except as provided in subsection (j), each licensee shall not annually produce more than an amount of product described by subsection (d) divided by the number of licensees.
- (g) In any fiscal year, licensees shall not have more live cannabis sativa plants than an amount authorized by the department in subsection (e) in this section divided by the number of licensees.
- (h) Licensees may report a forecasted shortage of product once in any quarter of the fiscal year to the department, which shall forward the report to the Department of State Health Services.
- (i) The Department of State Health Services may resend a revised report under subsection (b) at any time upon receipt of reliable information that conflicts with the most recently released report under subsection (b).
- (j) The department may increase the amount allowed under subsection (d) upon notice from the Department of State Health Services under subsection (i). An increase under this subsection is limited

to meeting the forecasted demand for product in Texas for the remainder of the current twelve (12) month period ending on the last day of August.

- (k) After the department makes a determination under subsection (j), each licensee may increase their maximum production allowed under subsection (f) of this section by the amount of the increase divided by the number of licensees or as otherwise determined by the department.
- (l) On March 1, 2018, the Department of State Health Services shall release updated population and dosage amounts required under subsection (b) that will determine the maximum amount of product allowed statewide under subsection (d)(1) of this subsection until September 1, 2018.
- (m) Subsection (l) expires on September 1, 2018.

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