

# Texas Department of Public Safety Regulatory Services Division

## Compassionate Use / Low-THC Cannabis Program Proposed Administrative Rules

**Proposed:**                    **37 Tex. Admin. Code 1, Chap.12**

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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, including any owner, involved in decisions governing the operation or daily functions of the licensed dispensing organization.
- (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 is cultivated, handled, transported, processed, or dispensed.
- (13) SOAH – State Office of Administrative Hearings.

**§12.2. Requirements and Standards.**

- (a) Licensees may only provide regulated services at the department approved 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 upon 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, including but not limited to the provision of any laboratory test results, employee records, or inventory and destruction records, and the compliance with any subpoena issued by the department.
- (f) Licensees and registrants may not cultivate, process, or dispense 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 or a qualified patient’s legal 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 services regulated under the Act for the 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, and the employer when notified by the employee or otherwise informed 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 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 services regulated under the Act must contain the license number.
- (m) Licensees must comply with all applicable local, state and federal regulations relating to air and environmental quality, fire safety, and noise or other nuisances.
- (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.
- (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.
- (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.

### **§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, 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 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) The records detailed in this subsection must be maintained by all licensees for two (2) years, unless otherwise provided:
  - (1) 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 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.
  - (4) Security records, including building access and visitor logs, and video recordings;
  - (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 years from the date employment is terminated.

**§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.
- (b) Licensees must test all processed products 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, 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.

**§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 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 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 low-THC cannabis to update inventory control 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 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.

## **Subchapter B            Application and Renewal**

### **§12.11. Application for License.**

- (a) Application for license as a dispensing organization may only be made through the department's online application process.
- (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 fees required under §12.14 of this title (relating to Application 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) 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 personnel 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 cannabis testing protocols and methods; and
  - (vi) A proposal establishing the ability to secure premises reasonably located to allow patient access through existing infrastructure.
- (C) The ability to maintain accountability of all raw materials, finished products, and any byproducts 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;
    - (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 low-THC source plant material throughout cultivation, processing, and dispensing;
  - (v) Inventory control system for low-THC cannabis 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) Personnel 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 the applicant, including any shareholders owning 10% or more 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) through (b)(5) of this section, and prior to approval of the application, the department will conduct an onsite inspection to confirm applicant's compliance with the requirements of subsection (b)(6) 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 ninety (90) 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 ninety (90) day period.
- (d) Failure of an applicant to submit all information and documentation required by subsection (b)(1) through (b)(5) 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 Fees and Method of Payment.**

- (a) The application fee for a dispensing organization license is \$6,000.
- (b) The fee for the biennial renewal of the dispensing organization license is \$6,000.
- (c) The registration application and biennial renewal fees are \$150.
- (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 onsite inspection, based on the failure to satisfy the requirements reflected in subsection (b)(6) of §12.11 of this title (relating to Application for License), and has either failed to address the basis for the failure within ninety (90) days of notice of the failure, or has failed to request an additional ninety (90) days to address the basis for the failure.
- (b) The department may also 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) 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.**

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 or a representative of an appropriate state 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 §§12.31 and 12.32 of this title (relating to Security of Facilities and Security of Vehicles, respectively);
  - (3) Records as provided in §12.4 of this title (relating to Records).
- (e) Failure to cooperate with an inspection by department 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.
- (e) Other than as provided in subsection (d) of this section, an individual whose license or registration has been revoked for a dishonored or reversed payment 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, a dispensing organization licensed under the Act may not allow access to the facility's low-THC cannabis area to unauthorized personnel or to the public. The licensee must establish and maintain a building, an enclosure within a building, or an

enclosed yard that provides reasonably adequate security 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.

- (c) Access to regulated premises by authorized personnel shall at a minimum be restricted by a physical barrier with a mechanical locking device that must be kept closed and locked at all times when not immediately being used to enter or exit the area. The area shall be clearly marked 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.
- (d) When unregistered individuals, whether personnel 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.

#### **§12.32. Security of Vehicles.**

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 personnel have access to the locked secure container within the vehicle.

#### **§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 jurisdiction and 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.

#### **§12.34. Reporting of Discrepancy, Loss or Theft.**

- (a) A licensee or registrant must report to the department not later than the second day following the date the licensee or registrant learns of:
  - (1) A notable inventory discrepancy;
  - (2) An inventory loss or theft; or

- (3) A loss or theft during transport.
- (b) The report required by subsection (a) of this section must reflect the name and registration or license number of the individual preparing the report, the date of the report, and the details listed in this subsection, as applicable:
  - (1) Date of discovery;
  - (2) Amount of low-THC cannabis involved, including amounts transported and received;
  - (3) Physical location at issue;
  - (4) Date transported, name of carrier or employee involved in the transport; or
  - (5) Description of any suspected criminal activity.

## **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 the purpose of 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 Registration**

- (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 confirm the patient has an active registration, the order has been entered in the registry by the physician, and the order has not already been dispensed.
- (b) The dispensing organization shall enter a dispensing action into the registry immediately upon dispensing the low-THC cannabis to the registered patient or the patient's legal guardian.

### **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.

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