



For issue of: PI Working ACK

Proposed Rulemaking Action

Agency Code: 0201

Title 37: Public Safety and Corrections

Part 1: Texas Department of Public Safety

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

Subchapter: B. Application and Renewal

Division:

TAC Section Number(s): §§12.11, 12.14, and 12.15

___ New ___ X ___ Amendment ___ Repeal

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

Common preamble: ___ Yes ___ X ___ No

File Name: CH12SubB

Graphics Included? ___ Yes ___ X ___ No

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

Verification/Certification

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

Agency Liaison: Duncan R. Fox or Susan Estringel

Certifying Official: D. Phillip Adkins

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Signature:

Date of Verification:

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The Texas Department of Public Safety (the department) proposes amendments to §§12.11, 12.14, and §12.15, concerning Application and Renewal. The proposed amendments to §12.11, concerning Application for License, requires that licensed dispensers of low-THC cannabis obtain commercial liability insurance within certain coverage limits, to ensure licensees can appropriately compensate third parties injured or otherwise harmed by the product or activities of the licensee. The proposed amendments to §12.14, concerning Applications Fees and Method of Payment, increase application and renewal fees to accurately reflect the costs of administering the program. The proposed amendments to §12.15, concerning Denial of Application for License, amend a cross reference necessitated by the proposed amendments to §12.11, and amend the bases for which the department may deny the application for a license in order to accurately reflect the requirements of Texas Health and Safety Code §487.104(a)(2).

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

Ms. Whittenton has determined that there will be no adverse economic effect on small businesses or micro-businesses required to comply with the proposed amendments to §12.15. There is no anticipated economic cost to businesses required to comply with the rule as proposed. There is no anticipated negative impact on local employment.

Ms. Whittenton has also determined that the proposed amendment to §12.11 may have adverse economic effects on small businesses required to comply with this rule as proposed. The department estimates there will be three licensees, and all of these licensees will be small businesses. These estimates are based on an analysis of other states' compassionate-use programs and the number of patients in Texas with intractable epilepsy, and Texas Health and Safety Code Chapter 487's requirements that the department issue at least three licenses and that issuance of the license be necessary to ensure reasonable statewide access to, and the availability of low-THC cannabis for patients for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code. The department estimates the projected impact of this rule will be increased costs of compliance associated with obtaining commercial liability insurance coverage. Specifically, the department estimates §12.11's requirement that dispensers obtain commercial liability insurance coverage will likely cost each licensee \$4,000 to \$5,000 per year.

In preparing these rules the department considered the alternatives of granting exemptions or grace periods from the requirements for small businesses. However, these rules are intended to implement Texas Health and Safety Code 487's requirements that, among other things, licensees possess the financial ability to maintain operations for not less than two years. The department's proposals also ensure licensees are financially capable of appropriately compensating third parties injured or otherwise harmed by the product or activities of the licensee. An exemption or grace period would be inconsistent with these purposes. There is no anticipated negative impact on local employment.

Ms. Whittenton has also determined that proposed rule §12.14, relating to application fees and method of payment, may have an adverse economic effect on small businesses required to comply with these rules as proposed. The department estimates there will be three licensees, with an average of thirty-seven registered employees per organization, and that all of these licensees will be small businesses. These estimates are based on an analysis of other states' compassionate-use programs, the number of patients in Texas with intractable epilepsy, and the Texas Health and Safety Code 487's requirements that the department issue at least three

licenses and that issuance of the license be necessary to ensure reasonable statewide access to, and the availability of low-THC cannabis for patients for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code. In calculating the costs of administering the statute, the department considered the type of employees to be involved with processing applications and inspecting facilities. A percentage of salary, fuels, consumables, and other operating costs are included. Also included are estimated costs for license cards; increased oversight of security; and FBI and state background checks. The estimated fee is \$1,300,000 per organization and \$4,820 per registrant, for initial licensure, and \$975,000 and \$2,875 respectively, for renewals. Because the proposed fees are based on the cost of administering the program, they are consistent with the statutory requirements. No alternative fees were considered because any variance would be inconsistent the health, safety, and environmental and economic welfare of the state.

In addition, Ms. Whittenton has also determined that for each year of the first five-year period the rules are in effect, the public benefit anticipated as a result of enforcing the rules will be greater protection of the public against harm or damages arising from licensees' industrial accidents or defective products.

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

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

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

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

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

<rule>

§12.11. 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) 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) [(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 employees [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 description of the proposed [cannabis] testing protocols and methods; [and]

(vi) A proposal establishing the ability to secure premises reasonably located to allow patient access through existing infrastructure; and [.]

(vii) Identification of the proposed source(s) for seeds or plants to be used in the cultivation of low-THC cannabis and of the manufacturers of all equipment to be used in the processing of low-THC cannabis.

(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 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 [low-THC] source seed and 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) Employee [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 any non-corporate [the] applicant, or all [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) – ~~(6)~~ [(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)(7)~~ [(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) – ~~(6)~~ [(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.

§12.14. Application Fees and Method of Payment.

(a) The application fee for a dispensing organization license is \$1,300,000 [~~\$6,000~~].

(b) The fee for the biennial renewal of the dispensing organization license is \$975,000 [~~\$6,000~~].

(c) The [registration] application fee for a registrant is \$4,820 and the fee for the [and] biennial renewal is \$2,875 [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)(7)~~ [(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) 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. Such determination may be based on the department's analysis of such factors as population distribution, the number patients with intractable epilepsy, any geographical disparities in the availability and cost of low-THC cannabis products, and the ability of the applicant to address such disparities or other observed deficiencies in access or availability.

(d) [(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.