BILL ANALYSIS

Senate Research Center 84R6525 GCB-F

S.B. 339 By: Eltife Health & Human Services 3/3/2015 As Filed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

According to the Epilepsy Foundation of Texas, there are approximately 149,000 Texans of all ages with intractable epilepsy, which means the condition is not controlled by medicine or surgical procedures. People with intractable epilepsy have a higher risk of a shortened life span, bodily injury, mental health impairment, and disability. Children with the condition experience developmental delays and some do not develop mentally past the stage of an infant.

Cannabidiol (CBD) oil is an extract from the cannabis plant, and has been shown to dramatically decrease the number of seizures in people with intractable epilepsy. The oil is produced to be high in CBD and low in tetrahydrocannabinol (THC), which is the intoxicating ingredient in the marijuana plant.

Eleven states have created programs to allow access to CBD oil for seizure disorders. S.B. 339 creates a regulatory mechanism for Texas to legalize and regulate the growth of cannabis plants high in CBD and low in THC. Patients could be given access to this medicine upon the recommendation of two board-certified medical specialists.

As proposed, S.B. 339 amends current law relating to the medical use of low-THC cannabis and the regulation of related organizations and individuals, requires a dispensing organization to obtain a license to dispense low-THC cannabis and any employee of a dispensing organization to obtain a registration, and authorizes fees.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the public safety director of the Texas Department of Public Safety in SECTION 1 (Sections 487.052 and 487.105, Health and Safety Code) of this bill

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle C, Title 6, Health and Safety Code, by adding Chapter 487, as follows:

CHAPTER 487. TEXAS COMPASSIONATE-USE ACT

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 487.001. DEFINITIONS. Defines "department," "director," "dispensing organization," "low-THC cannabis," and "nonprofit organization."

[Reserves Sections 487.002-487.050 for expansion.]

SUBCHAPTER B. DUTIES OF DEPARTMENT

Sec. 487.051. DUTIES OF DEPARTMENT. Requires the Department of Public Safety of the State of Texas (DPS) to administer this chapter.

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Sec. 487.052. RULES. Requires the public safety director of DPS (director) to adopt rules necessary for the administration and enforcement of this chapter, including rules imposing fees under this chapter in amounts sufficient to cover the cost of administering this chapter.

Sec. 487.053. LICENSING OF DISPENSING ORGANIZATIONS AND REGISTRATION OF CERTAIN ASSOCIATED INDIVIDUALS. (a) Requires DPS to issue or renew a license to operate as a dispensing organization to each applicant who satisfies the requirements established under this chapter and register directors, managers, and employees of each dispensing organization.

(b) Requires DPS to enforce compliance of licensees and registrants and to adopt procedures for suspending or revoking a license or registration issued under this chapter and for renewing a license or registration issued under this chapter.

Sec. 487.054. COMPASSIONATE-USE REGISTRY. (a) Requires DPS to establish and maintain a secure online compassionate-use registry that contains:

- (1) the name of each physician who registers as the prescriber for a patient under Section 169.003, Occupations Code, the name and date of birth of the patient, the dosage prescribed, the means of administration ordered, and the total amount of low-THC cannabis required to fill the patient's prescription; and
- (2) a record of each amount of low-THC cannabis dispensed by a dispensing organization to a patient under a prescription.
- (b) Requires DPS to ensure the registry:
 - (1) is designed to allow a physician qualified to prescribe low-THC cannabis under Section 169.002, Occupations Code, or dispensing organization to record information in the registry and prevent more than one qualified physician from registering as the prescriber for a single patient; and
 - (2) is accessible to law enforcement agencies and dispensing organizations 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.

[Reserves Sections 487.055-487.100 for expansion.]

SUBCHAPTER C. LICENSE TO OPERATE AS DISPENSING ORGANIZATION

Sec. 487.101. LICENSE REQUIRED. Provides that a license issued by DPS under this chapter is required to operate a dispensing organization.

Sec. 487.102. ELIGIBILITY FOR LICENSE. Provides that an applicant for a license to operate as a dispensing organization is eligible for the license if the applicant meets certain requirements. Sets forth the requirements for an applicant for a license to operate as a dispensing organization.

Sec. 487.103. APPLICATION. (a) Authorizes a nonprofit organization to apply for an initial or renewal license to operate as a dispensing organization by submitting a form prescribed by DPS along with the application fee in an amount set by the director.

(b) Requires that the application include the name and address of the applicant, the name and address of each director, manager, and employee, and any other information considered necessary by DPS to determine the applicant's eligibility for the license.

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Sec. 487.104. ISSUANCE, RENEWAL, OR DENIAL OF LICENSE. (a) Requires DPS to issue or renew a license to operate as a dispensing organization only if:

- (1) DPS determines the applicant meets the eligibility requirements described by Section 487.102; and
- (2) issuance or renewal of the license is 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.
- (b) Entitles an applicant, if DPS denies the issuance or renewal of a license under Subsection (a), to a hearing. Requires DPS to give written notice of the grounds for denial to the applicant at least 30 days before the hearing.
- (c) Provides that a license issued or renewed under this section expires on the second anniversary of the date of issuance or renewal, as applicable.
- Sec.487.105. CRIMINAL HISTORY BACKGROUND CHECK. (a) Requires an applicant for the issuance or renewal of a license to operate as a dispensing organization to provide DPS with the name of each of the applicant's directors, managers, and employees.
 - (b) Requires the licensee, before a dispensing organization licensee hires a manager or employee for the organization, to provide DPS with the name of the prospective manager or employee. Prohibits the licensee from transferring the license to another nonprofit organization before that prospective organization and its directors, managers, and employees pass a criminal background check and are registered as required by Subchapter D.
 - (c) Requires DPS to conduct a criminal history background check on each individual whose name is provided to DPS under Subsection (a) or (b). Requires the director by rule to:
 - (1) determine the manner by which an individual is required to submit a complete set of fingerprints to DPS for purposes of a criminal history background check under this section; and
 - (2) establish criteria for determining whether an individual passes the criminal history background check for the purposes of this section.
 - (d) Requires DPS, after conducting a criminal history background check under this section, to notify the relevant applicant or organization and the individual who is the subject of the criminal history background check as to whether the individual passed the criminal history background check.
- Sec. 487.106. DUTY TO MAINTAIN ELIGIBILITY. Requires a dispensing organization to maintain compliance at all times with the eligibility requirements described by Section 487.102.
- Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION. (a) Requires the dispensing organization, before dispensing low-THC cannabis to a person for whom the low-THC cannabis is prescribed under Chapter 169, Occupations Code, to verify the prescription presented meets certain requirements and sets forth those requirements.
 - (b) Requires the dispensing organization, after dispensing low-THC cannabis to a patient for whom the low-THC cannabis is prescribed under Chapter 169, Occupations Code, to record in the compassionate-use registry the form and quantity of low-THC cannabis dispensed and the date and time of dispensation.

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Sec. 487.108. LICENSE SUSPENSION OR REVOCATION. (a) Authorizes DPS to at any time suspend or revoke a license issued under this chapter if DPS determines that the licensee has not maintained the eligibility requirements described by Section 487.102 or has failed to comply with a duty imposed under this chapter.

- (b) Requires the director to give written notice to the dispensing organization of a license suspension or revocation under this section and the grounds for the suspension or revocation. Requires that the notice be sent by certified mail, return receipt requested.
- (c) Authorizes the director, after suspending or revoking a license issued under this chapter, to seize or place under seal all low-THC cannabis and drug paraphernalia owned or possessed by the dispensing organization. Prohibits a disposition from being made, if the director orders the revocation of the license, of the seized or sealed low-THC cannabis or drug paraphernalia until the time for administrative appeal of the order has elapsed or until all appeals have been concluded. Provides that all low-THC cannabis and drug paraphernalia, when a revocation order becomes final, may be forfeited to the state as provided under Subchapter E (Forfeiture), Chapter 481.
- (d) Provides that Chapter 2001 (Administrative Procedure), Government Code, applies to a proceeding under this section.

[Reserves Sections 487.109-487.150 for expansion.]

SUBCHAPTER D. REGISTRATION OF CERTAIN INDIVIDUALS

Sec. 487.151. REGISTRATION REQUIRED. (a) Requires an individual who is a director, manager, or employee of a dispensing organization to apply for and obtain a registration under this section.

- (b) Requires that an application for registration under this section meet certain requirements and sets forth those requirements.
- (c) Provides that a registration expires on the second anniversary of the date of the registration's issuance, unless suspended or revoked under rules adopted under this chapter.

[Reserves Sections 487.152-487.200 for expansion.]

SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT LOW-THC CANNABIS. Prohibits a municipality, county, or other political subdivision from enacting, adopting, or enforcing a rule, ordinance, order, resolution, or other regulation that prohibits the cultivation, production, dispensing, or possession of low-THC cannabis, as authorized by this chapter.

SECTION 2. Amends Section 481.062(a), Health and Safety Code, as follows:

- (a) Provides that the following persons are not required to register and may possess a controlled substance under this chapter:
 - (1)-(3) Makes no change to these subdivisions;
 - (4) Makes a nonsubstantive change to this subdivision;
 - (5) if the substance is tetrahydrocannabinol or one of its derivatives an official of the Department of State Health Services, rather than a Texas Department of

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Health official, a medical school researcher, or a research program participant possessing the substance as authorized under Subchapter G or a practitioner or an ultimate user possessing the substance as a participant in a federally approved therapeutic research program that the commissioner has reviewed and found, in writing, to contain a medically responsible research protocol; or

(6) a dispensing organization licensed under Chapter 487 that possesses low-THC cannabis.

SECTION 3. Amends Section 481.111, Health and Safety Code, by adding Subsections (e) and (f), as follows:

- (e) Provides that Sections 481.120, 481.121, 481.122, and 481.125 do not apply to a person who engages in the acquisition, possession, production, cultivation, delivery, or disposal of a raw material used in or by-product created by the production or cultivation of low-THC cannabis if the person meets certain requirements as set forth.
- (f) Defines "dispensing organization" and "low-THC cannabis" for purposes of Subsection (e).

SECTION 4. Amends Subtitle B, Title 3, Occupation Code, by adding Chapter 169, as follows:

CHAPTER 169. AUTHORITY TO PRESCRIBE LOW-THC CANNABIS TO CERTAIN PATIENTS FOR COMPASSIONATE USE

Sec. 169.001. DEFINITIONS. Defines "department," "intractable epilepsy," "low-THC cannabis," "medical use," and "smoking."

Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC CANNABIS. (a) Authorizes only a physician qualified as provided by this section to prescribe low-THC cannabis in accordance with this chapter.

(b) Provides that a physician is qualified to prescribe low-THC cannabis to a patient with intractable epilepsy if the physician meets certain requirements as set forth.

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. Authorizes a physician described by Section 169.002 to prescribe low-THC cannabis to alleviate a patient's seizures if certain criteria are met.

Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION. Requires a physician, before a physician qualified to prescribe low-THC cannabis under Section 169.002 may prescribe or renew a prescription for low-THC cannabis for a patient under this chapter, to register as the prescriber for that patient in the compassionate-use registry maintained by DPS under Section 487.054, Health and Safety Code. Requires that the physician's registration indicate the physician's name, the patient's name and date of birth, the dosage prescribed to the patient, the means of administration ordered for the patient, and the total amount of low-THC cannabis required to fill the patient's prescription.

Sec. 169.005. PATIENT TREATMENT PLAN. Requires a physician described by Section 169.002 who prescribes low-THC cannabis for a patient's medical use under this chapter to maintain a patient treatment plan that indicates the dosage, means of administration, and planned duration of treatment for the low-THC cannabis, a plan for monitoring the patient's symptoms, and a plan for monitoring indicators of tolerance or reaction to low-THC cannabis.

SECTION 5. Amends Section 551.004(a), Occupation Code, as follows:

(a) Provides that this subtitle does not apply to:

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- (1) and (2) Makes no change to these subdivisions;
- (3) and (4) Makes a nonsubstantive change to these subdivisions;
- (5) a dispensing organization, as defined by Section 487.001, Health and Safety Code, that cultivates, processes, and dispenses low-THC cannabis, as authorized by Chapter 487, Health and Safety Code, to a patient listed in the compassionate-use registry established under that chapter.
- SECTION 6. (a) Requires the director, not later than December 1, 2015, to adopt rules as required to implement, administer, and enforce Chapter 487, Health and Safety Code, as added by this Act, including rules to establish the compassionate-use registry required by that chapter.
 - (b) Requires DPS, not later than January 1, 2018, to license at least three dispensing organizations in accordance with Section 487.053, Health and Safety Code, as added by this Act, provided at least three applicants for a license to operate as a dispensing organization have met the requirements for approval provided by Subchapter C, Chapter 487, Health and Safety Code, as added by this Act.

SECTION 7. Effective date: upon passage or September 1, 2015.

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