

## **BILL ANALYSIS**

C.S.H.B. 892  
By: Klick  
Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

According to estimates of the Epilepsy Foundation of Texas, intractable epilepsy afflicts almost 150,000 people in this state. Concerned parties explain that patients with intractable epilepsy can suffer dozens or more severe seizures each week and that these individuals are at a higher risk for disability, injury, and even death. C.S.H.B. 892 seeks to regulate the growth and dispensation of low-THC cannabis for use in treating certain Texas residents diagnosed with intractable epilepsy.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that rulemaking authority is expressly granted to the public safety director of the Department of Public Safety in SECTION 1 of this bill.

### **ANALYSIS**

C.S.H.B. 892 amends the Occupations Code to authorize a qualified physician to prescribe low-THC cannabis to a patient with intractable epilepsy, defined by the bill as a seizure disorder in which the patient's seizures have been treated by two or more appropriately chosen and maximally titrated antiepileptic drugs that have failed to control the seizures. The bill establishes that a physician is qualified to prescribe low-THC cannabis to such a patient if the physician is licensed under the Medical Practice Act, dedicates a significant portion of clinical practice to the evaluation and treatment of epilepsy, and is certified by the appropriate certification board in epilepsy, neurophysiology, or neurology or neurology with special qualification in child neurology if the physician is otherwise qualified for the examination for certification in epilepsy.

C.S.H.B. 892 authorizes a qualified physician to prescribe low-THC cannabis to alleviate a patient's seizures if the patient is a permanent Texas resident; the physician complies with the bill's registration requirements; and the physician certifies to the Department of Public Safety (DPS) that the patient is diagnosed with intractable epilepsy, that the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient, and that a second qualified physician has concurred with that determination and the second physician's concurrence is recorded in the patient's medical record.

C.S.H.B. 892 requires a qualified physician, before the physician may prescribe or renew a prescription for low-THC cannabis for a patient, to register as the prescriber for that patient in the compassionate-use registry created under the bill and maintained by DPS and requires the registration to 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. The bill requires a qualified physician prescribing low-THC cannabis for a patient's medical use 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.

C.S.H.B. 892 amends the Health and Safety Code, including provisions amended by S.B. 219, Acts of the 84th Legislature, Regular Session, 2015, to require DPS to issue or renew a license to operate as a dispensing organization, defined by the bill as an organization licensed by DPS to cultivate, process, and dispense low-THC cannabis to a patient for whom low-THC cannabis is prescribed, to each applicant who satisfies the bill's requirements and to register directors, managers, and employees of each dispensing organization. The bill requires DPS to enforce compliance of licensees and registrants and to adopt procedures for suspending, revoking, and renewing a license or registration. The bill requires DPS to establish and maintain a secure online compassionate-use registry that contains specified information about a physician who registers as the prescriber of low-THC cannabis for a patient, about the patient prescribed such treatment, and about the patient's prescription and a record of each amount of low-THC cannabis dispensed by a dispensing organization to a patient under a prescription. The bill requires DPS to ensure the registry is designed to prevent more than one qualified physician from registering as the prescriber for a single patient, 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, and allows a qualified physician to input safety and efficacy data derived from the treatment of patients for whom low-THC cannabis is prescribed.

C.S.H.B. 892 requires a dispensing organization to obtain a license issued by DPS; sets out eligibility and application requirements for such a license; provides for the issuance, renewal, or denial of a license; and establishes provisions relating to the suspension or revocation of a license. The bill specifies that an original or renewal license to operate a dispensing organization expires on the second anniversary of the date of issuance or renewal as applicable and provides for a criminal history background check conducted by DPS of the applicant and all directors, managers, and employees of an applicant for a license to operate a dispensing organization. The bill requires the public safety director of DPS by rule to determine the manner by which an individual is required to submit a complete set of fingerprints to DPS for purposes of the background check and to establish criteria for determining whether an individual passes the background check.

C.S.H.B. 892 requires a dispensing organization, before dispensing low-THC cannabis to a person for whom the low-THC cannabis is prescribed, to verify that the prescription presented is for a person listed as a patient in the compassionate-use registry, matches the entry in the registry with respect to the total amount of low-THC cannabis required to fill the prescription, and has not previously been filled by a dispensing organization as indicated by an entry in the registry. The bill requires the dispensing organization, after dispensing low-THC cannabis to a patient for whom low-THC cannabis is prescribed, to record in the registry the form and quantity of low-THC cannabis dispensed and the date and time of dispensation. The bill requires an individual who is a director, manager, or employee of a dispensing organization to apply for and obtain a registration, sets out eligibility requirements for such a registration, and specifies that a registration expires on the second anniversary of the date of the registration's issuance unless suspended or revoked.

C.S.H.B. 892 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 the bill's provisions. The bill exempts a licensed dispensing organization that possesses low-THC cannabis from registration under the Texas Controlled Substances Act, authorizes such a dispensing organization to possess a controlled substance under the act, and exempts, under

certain conditions, 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 from offenses relating to the delivery or possession of marihuana, the delivery of a controlled substance or marihuana to a child, or the possession or delivery of drug paraphernalia.

C.S.H.B. 892 requires DPS to administer the bill's provisions regarding the licensing and registration of dispensing organizations and employees and requires the public safety director of DPS, not later than December 1, 2015, to adopt rules to implement, administer, and enforce those provisions, including rules to establish the compassionate-use registry. The bill requires DPS, not later than September 1, 2017, to license at least three dispensing organizations, provided at least three applicants for a license to operate as a dispensing organization have met the requirements for approval.

C.S.H.B. 892 amends the Occupations Code to exempt from the Texas Pharmacy Act a dispensing organization that cultivates, processes, and dispenses low-THC cannabis, as authorized by the bill's provisions, to a patient listed in the compassionate-use registry.

### **EFFECTIVE DATE**

On passage, or, if the bill does not receive the necessary vote, September 1, 2015.

### **COMPARISON OF ORIGINAL AND SUBSTITUTE**

While C.S.H.B. 892 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill and does not indicate differences relating to changes made by S.B. 219, Acts of the 84th Legislature, Regular Session, 2015, which became effective April 2, 2015.

#### **INTRODUCED**

SECTION 1. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 487 to read as follows:

CHAPTER 487. TEXAS  
COMPASSIONATE-USE ACT  
SUBCHAPTER A. GENERAL  
PROVISIONS

Sec. 487.001. DEFINITIONS. In this chapter:

(1) "Department" means the Department of Public Safety.

(2) "Director" means the public safety director of the department.

(3) "Dispensing organization" means a nonprofit organization licensed by the department to cultivate, process, and dispense low-THC cannabis to a patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.

(4) "Low-THC cannabis" has the meaning assigned by Section 169.001, Occupations Code.

(5) "Nonprofit organization" means any

#### **HOUSE COMMITTEE SUBSTITUTE**

SECTION 1. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 487 to read as follows:

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SUBCHAPTER A. GENERAL  
PROVISIONS

Sec. 487.001. DEFINITIONS. In this chapter:

(1) "Department" means the Department of Public Safety.

(2) "Director" means the public safety director of the department.

(3) "Dispensing organization" means an organization licensed by the department to cultivate, process, and dispense low-THC cannabis to a patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.

(4) "Low-THC cannabis" has the meaning assigned by Section 169.001, Occupations Code.

organization exempt from taxation under Section 501(a) of the Internal Revenue Code of 1986 as an organization described in Section 501(c) of that code.

SUBCHAPTER B. DUTIES OF DEPARTMENT  
Sec. 487.051. DUTIES OF DEPARTMENT.

Sec. 487.052. RULES.

Sec. 487.053. LICENSING OF DISPENSING ORGANIZATIONS AND REGISTRATION OF CERTAIN ASSOCIATED INDIVIDUALS.

Sec. 487.054. COMPASSIONATE-USE REGISTRY. (a) The department shall 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) The department shall ensure the registry:

(1) is designed to:

(A) 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

(B) 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.

SUBCHAPTER C. LICENSE TO OPERATE AS DISPENSING ORGANIZATION

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(2) a record of each amount of low-THC cannabis dispensed by a dispensing organization to a patient under a prescription.

(b) The department shall ensure the registry:

(1) is designed to prevent more than one qualified physician from registering as the prescriber for a single patient;

(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; and

(3) allows a physician qualified to prescribe low-THC cannabis under Section 169.002, Occupations Code, to input safety and efficacy data derived from the treatment of patients for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.

SUBCHAPTER C. LICENSE TO OPERATE AS DISPENSING ORGANIZATION

Sec. 487.101. LICENSE REQUIRED.

Sec. 487.102. ELIGIBILITY FOR LICENSE. An applicant for a license to operate as a dispensing organization is eligible for the license if:

- (1) the applicant is a nonprofit organization;
- (2) as determined by the department, the applicant possesses:
  - (A) the technical and technological ability to cultivate and produce low-THC cannabis;
  - (B) the ability to secure:
    - (i) the resources and personnel necessary to operate as a dispensing organization; and
    - (ii) premises reasonably located to allow patients listed on the compassionate-use registry access to the organization through existing infrastructure;
  - (C) the ability to maintain accountability for the raw materials, the finished product, and any by-products used or produced in the cultivation or production of low-THC cannabis to prevent unlawful access to or unlawful diversion or possession of those materials, products, or by-products; and
  - (D) the financial ability to maintain operations for not less than two years from the date of application;
- (3) each director, manager, or employee of the applicant is registered under Subchapter D; and
- (4) the applicant satisfies any additional criteria determined by the director to be necessary to safely implement this chapter.

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

(b) The application must 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 the department to determine the applicant's eligibility for the license.

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

- (1) the department determines the applicant meets the eligibility requirements described by Section 487.102; and

Sec. 487.101. LICENSE REQUIRED.

Sec. 487.102. ELIGIBILITY FOR LICENSE. An applicant for a license to operate as a dispensing organization is eligible for the license if:

- (1) as determined by the department, the applicant possesses:
  - (A) the technical and technological ability to cultivate and produce low-THC cannabis;
  - (B) the ability to secure:
    - (i) the resources and personnel necessary to operate as a dispensing organization; and
    - (ii) premises reasonably located to allow patients listed on the compassionate-use registry access to the organization through existing infrastructure;
  - (C) the ability to maintain accountability for the raw materials, the finished product, and any by-products used or produced in the cultivation or production of low-THC cannabis to prevent unlawful access to or unlawful diversion or possession of those materials, products, or by-products; and
  - (D) the financial ability to maintain operations for not less than two years from the date of application;
- (2) each director, manager, or employee of the applicant is registered under Subchapter D; and
- (3) the applicant satisfies any additional criteria determined by the director to be necessary to safely implement this chapter.

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

(b) The application must include the name and address of the applicant, the name and address of each of the applicant's directors, managers, and employees, and any other information considered necessary by the department to determine the applicant's eligibility for the license.

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

- (1) the department 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) If the department denies the issuance or renewal of a license under Subsection (a), the applicant is entitled to a hearing. The department shall give written notice of the grounds for denial to the applicant at least 30 days before the hearing.

(c) 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) An applicant for the issuance or renewal of a license to operate as a dispensing organization shall provide the department with the name of each of the applicant's directors, managers, and employees.

(b) Before a dispensing organization licensee hires a manager or employee for the organization, the licensee must provide the department with the name of the prospective manager or employee. The licensee may not transfer 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) The department shall conduct a criminal history background check on each individual whose name is provided to the department under Subsection (a) or (b). The director by rule shall:

(1) determine the manner by which an individual is required to submit a complete set of fingerprints to the department 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) After conducting a criminal history background check under this section, the department shall notify the relevant applicant or organization and the individual who is the subject of the criminal history

(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) If the department denies the issuance or renewal of a license under Subsection (a), the applicant is entitled to a hearing. The department shall give written notice of the grounds for denial to the applicant at least 30 days before the date of the hearing.

(c) 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) An applicant for the issuance or renewal of a license to operate as a dispensing organization shall provide the department with the applicant's name and the name of each of the applicant's directors, managers, and employees.

(b) Before a dispensing organization licensee hires a manager or employee for the organization, the licensee must provide the department with the name of the prospective manager or employee. The licensee may not transfer the license to another person before that prospective applicant and the applicant's directors, managers, and employees pass a criminal history background check and are registered as required by Subchapter D.

(c) The department shall conduct a criminal history background check on each individual whose name is provided to the department under Subsection (a) or (b). The director by rule shall:

(1) determine the manner by which an individual is required to submit a complete set of fingerprints to the department 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) After conducting a criminal history background check under this section, the department shall 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.

Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION.

Sec. 487.108. LICENSE SUSPENSION OR REVOCATION.

SUBCHAPTER D. REGISTRATION OF CERTAIN INDIVIDUALS

Sec. 487.151. REGISTRATION REQUIRED.

SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT LOW-THC CANNABIS.

SECTION 2. Section 481.062(a), Health and Safety Code, is amended.

SECTION 3. Section 481.111, Health and Safety Code, is amended.

SECTION 4. Subtitle B, Title 3, Occupations Code, is amended by adding Chapter 169 to read as follows:

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

Sec. 169.001. DEFINITIONS.

Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC CANNABIS.

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A physician described by Section 169.002 may prescribe low-THC cannabis to alleviate a patient's seizures if:

(1) the patient is a permanent resident of the state;

(2) the physician complies with the registration requirements of Section 169.004; and

(3) the physician certifies to the department that:

(A) the patient is diagnosed with intractable epilepsy;

background check as to whether the individual passed the criminal history background check.

Sec. 487.106. DUTY TO MAINTAIN ELIGIBILITY.

Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION.

Sec. 487.108. LICENSE SUSPENSION OR REVOCATION.

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Sec. 487.151. REGISTRATION REQUIRED.

SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT LOW-THC CANNABIS.

SECTION 2. Substantially the same as introduced version.

SECTION 3. Same as introduced version.

SECTION 4. Subtitle B, Title 3, Occupations Code, is amended by adding Chapter 169 to read as follows:

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

Sec. 169.001. DEFINITIONS.

Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC CANNABIS.

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A physician described by Section 169.002 may prescribe low-THC cannabis to alleviate a patient's seizures if:

(1) the patient is a permanent resident of the state;

(2) the physician complies with the registration requirements of Section 169.004; and

(3) the physician certifies to the department that:

(A) the patient is diagnosed with intractable epilepsy;

(B) the physician has provided two or more different treatments approved by the United States Food and Drug Administration and the provided treatments have not alleviated the patient's seizures;

(C) no other treatment options approved by the United States Food and Drug Administration are available or appropriate for the patient;

(D) the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient; and

(E) if the patient is younger than 18 years of age:

(i) a second physician qualified to prescribe low-THC cannabis under Section 169.002 has concurred with the determination under Paragraph (D); and

(ii) the second physician's concurrence is recorded in the patient's medical record.

Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION.

Sec. 169.005. PATIENT TREATMENT PLAN.

SECTION 5. Section 551.004(a), Occupations Code, is amended.

SECTION 6. (a) Not later than December 1, 2015, the public safety director of the Department of Public Safety shall 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) Not later than January 1, 2018, the Department of Public Safety shall 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. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article

(B) the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient; and

(C) a second physician qualified to prescribe low-THC cannabis under Section 169.002 has concurred with the determination under Paragraph (B), and the second physician's concurrence is recorded in the patient's medical record.

Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION.

Sec. 169.005. PATIENT TREATMENT PLAN.

SECTION 5. Same as introduced version.

SECTION 6. (a) Not later than December 1, 2015, the public safety director of the Department of Public Safety shall 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) Not later than September 1, 2017, the Department of Public Safety shall 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. Same as introduced version.



III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2015.