Eltife, Ellis, Rodríguez 1-1 By: S.B. No. 339 (In the Senate - Filed January 23, 2015; February 2, 2015, first time and referred to Committee on State Affairs; 1-2 1-3 read February 18, 2015, rereferred to Committee on Health and Human Services; May 5, 2015, reported adversely, with favorable 1-4 1-5 Committee Substitute by the following vote: Yeas 8, Nays 1; 1-6 1 - 7May 5, 2015, sent to printer.)

1-8 COMMITTEE VOTE

1-9		Yea	Nay	Absent	PNV
1-10	Schwertner	Χ	-		
1-11	Kolkhorst	X			
1-12	Campbell	X			
1-13	Estes	X			
1-14	Perry	X			
1-15	Rodríguez	X			
1-16	Taylor of Collin		Χ		
1-17	Uresti	X			
1-18	Zaffirini	X			

COMMITTEE SUBSTITUTE FOR S.B. No. 339 By: 1-19 Schwertner

## 1-20 A BILL TO BE ENTITLED 1-21 AN ACT

relating to the medical use of low-THC cannabis and the regulation of related organizations and individuals; requiring a dispensing organization to obtain a license to dispense low-THC cannabis and any employee of a dispensing organization to obtain a registration; authorizing fees.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

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
O1. DEFINITIONS. In this chapter: 001.

"Department" means the Department (1)

Safety.

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(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 m
Section 169.001, Occupations Code. meaning assigned

SUBCHAPTER B. DUTIES OF DEPARTMENT

Sec. 487.051. DUTIES OF DEPARTMENT. The department shall administer this chapter.

Sec. 487.052. RULES. The director shall adopt any 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 CERTAIN ASSOCIATED INDIVIDUALS. (a)

department shall:

(1) issue or renew a license to operate as a dispensing organization to each applicant who satisfies the requirements established under this chapter; and

(2) register directors, managers, and employees of

each dispensing organization. 1-57

1-58 (b) The department shall enforce compliance of licensees and registrants and shall adopt procedures for suspending or revoking a license or registration issued under this chapter and 1-59 1-60

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C.S.S.B. No. 339
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for renewing a license or registration issued under this chapter.
2-1
           Sec. 487.054. COMPASSIONATE-USE REGISTRY.
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                                                              (a)
                 shall
                                                                online
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                         establish and maintain
     department
                                                   а
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     compassionate-use registry that contains:
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(1) the name of each physician who registers as the for a patient under Section 169.004, Occupations Code, the name and date of birth of the patient, the dosage prescribed, means of administration ordered, and the total amount

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 prescription.

(b) The department shall ensure the registry:

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(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. A license issued by the department under this chapter is required to operate a dispensing

organization. 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:

the technical and technological ability to (A) 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

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.

APPLICATION. (a) A person may apply for an Sec. 487.103. 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.

RENEWAL, Sec. 487.104. ISSUANCE, OR DENIAL OF LICENSE. 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

issuance or renewal of the license is necessary to (2) ensure reasonable statewide access to, and the availability of, low-THC cannabis for patients registered in the compassionate-use

C.S.S.B. No. 339

registry and for whom low-THC cannabis is prescribed under Chapter 3 - 13-2 169, Occupations Code.

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(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.

CRIMINAL HISTORY BACKGROUND CHECK. 487.105. Sec. 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.

Before a dispensing organization licensee hires (b) manager or employee for the organization, the licensee must provide the department with the name of the prospective manager or The licensee may not transfer the license to another employee. person before that prospective applicant and the applicant's a criminal history directors, managers, and employees pass 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. organization must maintain compliance at all times with the eligibility requirements described by Section 487.102.

Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION.

Before dispensing low-THC cannabis to a person for whom the low-THC cannabis is prescribed under Chapter 169, Occupations Code, the dispensing organization must verify that the prescription presented:

is a person listed as a patient in the for compassionate-use registry;

(2) matches the entry in the compassionate-use with respect to the total amount of low-THC cannabis registry

required to fill the prescription; and
(3) has not previously been filled by a dispensing organization as indicated by an entry in the compassionate-use registry.

(b) After dispensing low-THC cannabis to a patient for whom the low-THC cannabis is prescribed under Chapter 169, Occupations Code, the dispensing organization shall record in the compassionate-use registry the form and quantity of low-THC cannabis dispensed and the date and time of dispensation.

Sec. 487.108. LICENSE SUSPENSION OR REVOCATION. The (a) department may at any time suspend or revoke a license issued under this chapter if the department 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) The director shall give written notice to the dispensing organization of a license suspension or revocation under this section and the grounds for the suspension or revocation. notice must be sent by certified mail, return receipt requested.

(c) After suspending or revoking a license issued under this

chapter, the director may seize or place under seal all low-THC cannabis and drug paraphernalia owned or possessed by the dispensing organization. If the director and in the director are all the directors are all the directors are all the directors are all the directors. dispensing organization. If the director orders the revocation of the license, a disposition may not be made 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. When a revocation order becomes final, all low-THC cannabis and drug paraphernalia may be forfeited to the state as provided under Subchapter E, Chapter 481.

(d) Chapter 2001, Government Code, applies to a proceeding

under this section.

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SUBCHAPTER D. REGISTRATION OF CERTAIN INDIVIDUALS

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

(b) An applicant for a registration under this section must:

(1) be at least 18 years of age;

submit a complete set of fingerprints to the department in the manner required by department rule; and

(3) pass a fingerprint-based criminal history

background check as required by Section 487.105.

(c) A registration expires on the second anniversary of the of the registration's issuance, unless suspended or revoked under rules adopted under this chapter.

SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT

LOW-THC CANNABIS. A municipality, county, or other political subdivision may not enact, adopt, or enforce 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. Section 481.062(a), Health and Safety Code, as amended by S.B. 219, Acts of the 84th Legislature, Regular Session,

2015, is amended to read as follows:

(a) The following persons are not required to register and may possess a controlled substance under this chapter:

(1) an agent or employee of a registered manufacturer, distributor, analyzer, or dispenser of the controlled substance acting in the usual course of business or employment;

(2) a common or contract carrier, a warehouseman, or an employee of a carrier or warehouseman whose possession of the controlled substance is in the usual course of business or employment;

(3) an ultimate user or a person in possession of the controlled substance under a lawful order of a practitioner or in lawful possession of the controlled substance if it is listed in Schedule V;

- (4) an officer or employee of this state, another state, a political subdivision of this state or another state, or the United States who is lawfully engaged in the enforcement of a law relating to a controlled substance or drug or to a customs law and authorized to possess the controlled substance in the discharge of the person's official duties; [or]
- (5) if the substance is tetrahydrocannabinol or one of its derivatives:
- (A) a Department of State Health Services official, a medical school researcher, or a research program  $% \left( A\right) =A\left( A\right) +A\left( A$ participant possessing the substance as authorized Subchapter G; or
- (B) 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. Section 481.111, Health and Safety Code, is

amended by adding Subsections (e) and (f) to read as follows:

(e) Sections 481.120, 481.121, 481.122, and 481.125 do not

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C.S.S.B. No. 339
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:
               (1) for an offense involving possession only
                                                                                of
marihuana or drug paraphernalia, is a patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code, or the
patient's legal guardian, and the person possesses low-THC cannabis
obtained under a valid prescription from a dispensing organization;
(2) is a director, manager, or employee of a dispensing organization and the person, solely in performing the
person's regular duties at the organization, acquires, possesses,
produces, cultivates, dispenses, or disposes of:
                                 reasonable
                                                 quantities,
                     (A)
                           in
                                                                   any
                                                                          low-THC
cannabis or raw materials used in or by-products created by the
production or cultivation of low-THC cannabis; or
                     (B) any drug paraphernalia
acquisition, possession, linesal of low-THC cannabis.
                                 production, cultivation, delivery,
                                                                               or
              For purposes of Subsection (e):
                     "Dispensing organization"
              (1)
                                                          has the meaning
assigned by Section 487.001.
(2) "Low-THC cannabis" has the meaning assigned Section 169.001, Occupations Code.

SECTION 4. Subtitle B, Title 3, Occupations Code,
                    "Low-THC cannabis" has the meaning assigned by
amended by adding Chapter 169 to read as follows:
  CHAPTER 169. AUTHORITY TO PRESCRIBE LOW-THC CANNABIS TO CERTAIN
                      PATIENTS FOR COMPASSIONATE USE
              169.001. DEFINITIONS. In this chapter:
(1) "Department" means the Department
                                               the Department of Public
Safety.
(2) "Intractable epilepsy" means 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.
               (3) "Low-THC cannabis" means the plant Cannabis sativa
     and any part of that plant or any compound, manufacture, salt,
derivative, mixture, preparation, resin, or oil of that plant that
contains:
                           <u>no</u>t
                                 more than 0.5 percent by weight
                     (A)
                                                                                <u>o</u>f
tetrahydrocannabinols; and
                     (B) not
                                  less than 10 percent by weight
cannabidiol.
(4) "Medical use" means the ingestion by a means of administration other than by smoking of a prescribed amount of
low-THC cannabis by a person for whom low-THC cannabis
                                                                                is
prescribed under this chapter.
                    "Smoking" means burning or igniting a substance
              (5)
and inhaling the
                    smoke.
       Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE
              (a) Only a physician qualified as provided by this
section may prescribe low-THC cannabis in accordance with this
chapter.
(b) A physician is qualified to prescribe low-THC cannabis to a patient with intractable epilepsy if the physician:
               (1)
                     is licensed under this subtitle;
               (2)
                     dedicates a significant portion of
                                                                        clinical
practice to the evaluation and treatment of epilepsy; and
                     is certified:
(A) by the American Board of Psychiatry and
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Neurology in:

(i) epilepsy; or (ii) neurology or neurology with special qualification in child neurology and is otherwise qualified for the

examination for certification in epilepsy; or (B) in neurophysiology by:

(i) the American Board of Psychiatry and

Neurology; or

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C.S.S.B. No. 339
Board of Clinical
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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:

(ii) the American

(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 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. 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, the physician must register as the prescriber for that patient in the compassionate-use registry maintained by the department under Section 487.054, Health and Safety Code. The physician's registration must indicate:

(1) the physician's name;

(2) the patient's name and date of birth;(3) the dosage prescribed to the patient;

(4) the means of administration ordered for the

patient; and

(5) the total amount of low-THC cannabis required to fill the patient's prescription.

A physician

Sec. 169.005. PATIENT TREATMENT PLAN. A physician described by Section 169.002 who prescribes low-THC cannabis for a patient's medical use under this chapter must maintain a patient treatment plan that indicates:

(1) the dosage, means of administration, and planned duration of treatment for the low-THC cannabis;

(2) a plan for monitoring the patient's symptoms; and(3) a plan for monitoring indicators of tolerance or

reaction to low-THC cannabis.

SECTION 5. Section 551.004(a), Occupations Code, is amended to read as follows:

(a) This subtitle does not apply to:

(1) a practitioner licensed by the appropriate state board who supplies a patient of the practitioner with a drug in a manner authorized by state or federal law and who does not operate a pharmacy for the retailing of prescription drugs;

pharmacy for the retailing of prescription drugs;

(2) a member of the faculty of a college of pharmacy recognized by the board who is a pharmacist and who performs the

pharmacist's services only for the benefit of the college;

(3) a person who procures prescription drugs for lawful research, teaching, or testing and not for resale;  $[\frac{\partial r}{\partial x}]$ 

(4) a home and community support services agency that possesses a dangerous drug as authorized by Section 142.0061, 142.0062, or 142.0063, Health and Safety Code; or

(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) 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

C.S.S.B. No. 339

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

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

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