By: Eltife S.B. No. 339

A BILL TO BE ENTITLED

| 1 | AN ACT |
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| 2 | relating to the medical use of low-THC cannabis and the regulation |
| 3 | of related organizations and individuals; requiring a dispensing |
| 4 | organization to obtain a license to dispense low-THC cannabis and |
| 5 | any employee of a dispensing organization to obtain a registration; |
| 6 | authorizing fees. |
| 7 | BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: |
| 8 | SECTION 1. Subtitle C, Title 6, Health and Safety Code, is |
| 9 | amended by adding Chapter 487 to read as follows: |
| 10 | CHAPTER 487. TEXAS COMPASSIONATE-USE ACT |
| 11 | SUBCHAPTER A. GENERAL PROVISIONS |
| 12 | Sec. 487.001. DEFINITIONS. In this chapter: |
| 13 | (1) "Department" means the Department of Public |
| 14 | Safety. |
| 15 | (2) "Director" means the public safety director of the |
| 16 | department. |
| 17 | (3) "Dispensing organization" means a nonprofit |
| 18 | organization licensed by the department to cultivate, process, and |
| 19 | dispense low-THC cannabis to a patient for whom low-THC cannabis is |
| 20 | prescribed under Chapter 169, Occupations Code. |
| 21 | (4) "Low-THC cannabis" has the meaning assigned by |
| 22 | Section 169.001, Occupations Code. |
| 23 | (5) "Nonprofit organization" means any organization |
| 24 | exempt from taxation under Section 501(a) of the Internal Revenue |

- 1 Code of 1986 as an organization described in Section 501(c) of that
- 2 code.
- 3 SUBCHAPTER B. DUTIES OF DEPARTMENT
- 4 Sec. 487.051. DUTIES OF DEPARTMENT. The department shall
- 5 administer this chapter.
- 6 Sec. 487.052. RULES. The director shall adopt any rules
- 7 necessary for the administration and enforcement of this chapter,
- 8 including rules imposing fees under this chapter in amounts
- 9 sufficient to cover the cost of administering this chapter.
- 10 Sec. 487.053. LICENSING OF DISPENSING ORGANIZATIONS AND
- 11 REGISTRATION OF CERTAIN ASSOCIATED INDIVIDUALS. (a) The
- 12 department shall:
- 13 (1) issue or renew a license to operate as a dispensing
- 14 organization to each applicant who satisfies the requirements
- 15 <u>established under this chapter; and</u>
- 16 (2) register directors, managers, and employees of
- 17 each dispensing organization.
- 18 (b) The department shall enforce compliance of licensees
- 19 and registrants and shall adopt procedures for suspending or
- 20 revoking a license or registration issued under this chapter and
- 21 for renewing a license or registration issued under this chapter.
- Sec. 487.054. COMPASSIONATE-USE REGISTRY. (a) The
- 23 department shall establish and maintain a secure online
- 24 compassionate-use registry that contains:
- 25 (1) the name of each physician who registers as the
- 26 prescriber for a patient under Section 169.003, Occupations Code,
- 27 the name and date of birth of the patient, the dosage prescribed,

the means of administration ordered, and the total amount of 1 2 low-THC cannabis required to fill the patient's prescription; and (2) a record of each amount of low-THC cannabis 3 dispensed by a dispensing organization to a patient under a 4 5 prescription. 6 The department shall ensure the registry: (b) 7 (1) is designed to: 8 (A) allow a physician qualified to prescribe low-THC cannabis under Section 169.002, Occupations Code, or 9 10 dispensing organization to record information in the registry; and (B) prevent more than one qualified physician 11 12 from registering as the prescriber for a single patient; and (2) is accessible to law enforcement agencies and 13 14 dispensing organizations for the purpose of verifying whether a 15 patient is one for whom low-THC cannabis is prescribed and whether the patient's prescriptions have been filled. 16 17 SUBCHAPTER C. LICENSE TO OPERATE AS DISPENSING ORGANIZATION Sec. 487.101. LICENSE REQUIRED. A license issued by the 18 19 department under this chapter is required to operate a dispensing 20 organization. 21 Sec. 487.102. ELIGIBILITY FOR LICENSE. An applicant for a 22 license to operate as a dispensing organization is eligible for the 23 license if: 24 (1) the applicant is a nonprofit organization; 25 (2) as determined by the department, the applicant

(A) the technical and technological ability to

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possesses:

| 1 | cultivate and produce low-THC cannabis; |
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| 2 | (B) the ability to secure: |
| 3 | (i) the resources and personnel necessary |
| 4 | to operate as a dispensing organization; and |
| 5 | (ii) premises reasonably located to allow |
| 6 | patients listed on the compassionate-use registry access to the |
| 7 | organization through existing infrastructure; |
| 8 | (C) the ability to maintain accountability for |
| 9 | the raw materials, the finished product, and any by-products used |
| 10 | or produced in the cultivation or production of low-THC cannabis to |
| 11 | prevent unlawful access to or unlawful diversion or possession of |
| 12 | those materials, products, or by-products; and |
| 13 | (D) the financial ability to maintain operations |
| 14 | for not less than two years from the date of application; |
| 15 | (3) each director, manager, or employee of the |
| 16 | applicant is registered under Subchapter D; and |
| 17 | (4) the applicant satisfies any additional criteria |
| 18 | determined by the director to be necessary to safely implement this |
| 19 | <u>chapter.</u> |
| 20 | Sec. 487.103. APPLICATION. (a) A nonprofit organization |
| 21 | may apply for an initial or renewal license to operate as a |
| 22 | dispensing organization by submitting a form prescribed by the |
| 23 | department along with the application fee in an amount set by the |
| 24 | director. |
| 25 | (b) The application must include the name and address of the |
| 26 | applicant, the name and address of each director, manager, and |
| 27 | employee, and any other information considered necessary by the |

- 1 department to determine the applicant's eligibility for the
- 2 license.
- 3 Sec. 487.104. ISSUANCE, RENEWAL, OR DENIAL OF LICENSE. (a)
- 4 The department shall issue or renew a license to operate as a
- 5 dispensing organization only if:
- 6 (1) the department determines the applicant meets the
- 7 eligibility requirements described by Section 487.102; and
- 8 (2) issuance or renewal of the license is necessary to
- 9 ensure reasonable statewide access to, and the availability of,
- 10 low-THC cannabis for patients registered in the compassionate-use
- 11 registry and for whom low-THC cannabis is prescribed under Chapter
- 12 169, Occupations Code.
- 13 (b) If the department denies the issuance or renewal of a
- 14 license under Subsection (a), the applicant is entitled to a
- 15 hearing. The department shall give written notice of the grounds
- 16 for denial to the applicant at least 30 days before the hearing.
- 17 <u>(c)</u> A license issued or renewed under this section expires
- 18 on the second anniversary of the date of issuance or renewal, as
- 19 applicable.
- Sec. 487.105. CRIMINAL HISTORY BACKGROUND CHECK. (a) An
- 21 applicant for the issuance or renewal of a license to operate as a
- 22 dispensing organization shall provide the department with the name
- 23 of each of the applicant's directors, managers, and employees.
- 24 (b) Before a dispensing organization licensee hires a
- 25 manager or employee for the organization, the licensee must provide
- 26 the department with the name of the prospective manager or
- 27 employee. The licensee may not transfer the license to another

- 1 nonprofit organization before that prospective organization and
- 2 its directors, managers, and employees pass a criminal background
- 3 check and are registered as required by Subchapter D.
- 4 (c) The department shall conduct a criminal history
- 5 background check on each individual whose name is provided to the
- 6 department under Subsection (a) or (b). The director by rule shall:
- 7 (1) determine the manner by which an individual is
- 8 required to submit a complete set of fingerprints to the department
- 9 for purposes of a criminal history background check under this
- 10 section; and
- 11 (2) establish criteria for determining whether an
- 12 individual passes the criminal history background check for the
- 13 purposes of this section.
- 14 (d) After conducting a criminal history background check
- 15 under this section, the department shall notify the relevant
- 16 applicant or organization and the individual who is the subject of
- 17 the criminal history background check as to whether the individual
- 18 passed the criminal history background check.
- 19 Sec. 487.106. DUTY TO MAINTAIN ELIGIBILITY. A dispensing
- 20 organization must maintain compliance at all times with the
- 21 eligibility requirements described by Section 487.102.
- 22 <u>Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION.</u>
- 23 (a) Before dispensing low-THC cannabis to a person for whom the
- 24 low-THC cannabis is prescribed under Chapter 169, Occupations Code,
- 25 the dispensing organization must verify that the prescription
- 26 presented:
- 27 (1) is for a person listed as a patient in the

- 1 compassionate-use registry;
- 2 (2) matches the entry in the compassionate-use
- 3 registry with respect to the total amount of low-THC cannabis
- 4 required to fill the prescription; and
- 5 (3) has not previously been filled by a dispensing
- 6 organization as indicated by an entry in the compassionate-use
- 7 <u>registry.</u>
- 8 (b) After dispensing low-THC cannabis to a patient for whom
- 9 the low-THC cannabis is prescribed under Chapter 169, Occupations
- 10 Code, the dispensing organization shall record in the
- 11 compassionate-use registry the form and quantity of low-THC
- 12 cannabis dispensed and the date and time of dispensation.
- Sec. 487.108. LICENSE SUSPENSION OR REVOCATION. (a) The
- 14 department may at any time suspend or revoke a license issued under
- 15 this chapter if the department determines that the licensee has not
- 16 maintained the eligibility requirements described by Section
- 17 487.102 or has failed to comply with a duty imposed under this
- 18 chapter.
- 19 (b) The director shall give written notice to the dispensing
- 20 organization of a license suspension or revocation under this
- 21 section and the grounds for the suspension or revocation. The
- 22 <u>notice must be sent by certified mail, return receipt requested.</u>
- 23 (c) After suspending or revoking a license issued under this
- 24 chapter, the director may seize or place under seal all low-THC
- 25 cannabis and drug paraphernalia owned or possessed by the
- 26 dispensing organization. If the director orders the revocation of
- 27 the license, a disposition may not be made of the seized or sealed

- 1 low-THC cannabis or drug paraphernalia until the time for
- 2 administrative appeal of the order has elapsed or until all appeals
- 3 have been concluded. When a revocation order becomes final, all
- 4 low-THC cannabis and drug paraphernalia may be forfeited to the
- 5 state as provided under Subchapter E, Chapter 481.
- 6 (d) Chapter 2001, Government Code, applies to a proceeding
- 7 under this section.
- 8 SUBCHAPTER D. REGISTRATION OF CERTAIN INDIVIDUALS
- 9 Sec. 487.151. REGISTRATION REQUIRED. (a) An individual
- 10 who is a director, manager, or employee of a dispensing
- 11 organization must apply for and obtain a registration under this
- 12 section.
- 13 (b) An applicant for a registration under this section must:
- 14 (1) be at least 18 years of age;
- 15 (2) submit a complete set of fingerprints to the
- 16 <u>department in the manner required by department rule; and</u>
- 17 (3) pass a fingerprint-based criminal history
- 18 background check as required by Section 487.105.
- 19 (c) A registration expires on the second anniversary of the
- 20 date of the registration's issuance, unless suspended or revoked
- 21 <u>under rules adopted under this chapter.</u>
- 22 <u>SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES</u>
- Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT
- 24 LOW-THC CANNABIS. A municipality, county, or other political
- 25 subdivision may not enact, adopt, or enforce a rule, ordinance,
- 26 order, resolution, or other regulation that prohibits the
- 27 cultivation, production, dispensing, or possession of low-THC

- 1 cannabis, as authorized by this chapter.
- 2 SECTION 2. Section 481.062(a), Health and Safety Code, is
- 3 amended to read as follows:
- 4 (a) The following persons are not required to register and
- 5 may possess a controlled substance under this chapter:
- 6 (1) an agent or employee of a registered manufacturer,
- 7 distributor, analyzer, or dispenser of the controlled substance
- 8 acting in the usual course of business or employment;
- 9 (2) a common or contract carrier, a warehouseman, or
- 10 an employee of a carrier or warehouseman whose possession of the
- 11 controlled substance is in the usual course of business or
- 12 employment;
- 13 (3) an ultimate user or a person in possession of the
- 14 controlled substance under a lawful order of a practitioner or in
- 15 lawful possession of the controlled substance if it is listed in
- 16 Schedule V;
- 17 (4) an officer or employee of this state, another
- 18 state, a political subdivision of this state or another state, or
- 19 the United States who is lawfully engaged in the enforcement of a
- 20 law relating to a controlled substance or drug or to a customs law
- 21 and authorized to possess the controlled substance in the discharge
- 22 of the person's official duties; [or]
- 23 (5) if the substance is tetrahydrocannabinol or one of
- 24 its derivatives:
- 25 (A) an [a Texas Department of Health] official of
- 26 the Department of State Health Services, a medical school
- 27 researcher, or a research program participant possessing the

- 1 substance as authorized under Subchapter G; or
- 2 (B) a practitioner or an ultimate user possessing
- 3 the substance as a participant in a federally approved therapeutic
- 4 research program that the commissioner has reviewed and found, in
- 5 writing, to contain a medically responsible research protocol; or
- 6 (6) a dispensing organization licensed under Chapter
- 7 487 that possesses low-THC cannabis.
- 8 SECTION 3. Section 481.111, Health and Safety Code, is
- 9 amended by adding Subsections (e) and (f) to read as follows:
- 10 (e) Sections 481.120, 481.121, 481.122, and 481.125 do not
- 11 apply to a person who engages in the acquisition, possession,
- 12 production, cultivation, delivery, or disposal of a raw material
- 13 used in or by-product created by the production or cultivation of
- 14 low-THC cannabis if the person:
- 15 (1) for an offense involving possession only of
- 16 marihuana or drug paraphernalia, is a patient for whom low-THC
- 17 cannabis is prescribed under Chapter 169, Occupations Code, or the
- 18 patient's legal guardian, and the person possesses low-THC cannabis
- 19 obtained under a valid prescription from a dispensing organization;
- 20 or
- 21 (2) is a director, manager, or employee of a
- 22 dispensing organization and the person, solely in performing the
- 23 person's regular duties at the organization, acquires, possesses,
- 24 produces, cultivates, dispenses, or disposes of:
- (A) in reasonable quantities, any low-THC
- 26 cannabis or raw materials used in or by-products created by the
- 27 production or cultivation of low-THC cannabis; or

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- 1 (B) any drug paraphernalia used in the
- 2 acquisition, possession, production, cultivation, delivery, or
- 3 <u>disposal of low-THC cannabis.</u>
- 4 (f) For purposes of Subsection (e):
- 5 (1) "Dispensing organization" has the meaning
- 6 assigned by Section 487.001.
- 7 (2) "Low-THC cannabis" has the meaning assigned by
- 8 Section 169.001, Occupations Code.
- 9 SECTION 4. Subtitle B, Title 3, Occupations Code, is
- 10 amended by adding Chapter 169 to read as follows:
- 11 CHAPTER 169. AUTHORITY TO PRESCRIBE LOW-THC CANNABIS TO CERTAIN
- 12 PATIENTS FOR COMPASSIONATE USE
- Sec. 169.001. DEFINITIONS. In this chapter:
- 14 (1) "Department" means the Department of Public
- 15 <u>Safety.</u>
- 16 (2) "Intractable epilepsy" means a seizure disorder in
- 17 which the patient's seizures have been treated by two or more
- 18 appropriately chosen and maximally titrated antiepileptic drugs
- 19 that have failed to control the seizures.
- 20 (3) "Low-THC cannabis" means the plant Cannabis sativa
- 21 L., and any part of that plant or any compound, manufacture, salt,
- 22 derivative, mixture, preparation, resin, or oil of that plant that
- 23 contains:
- (A) not more than 0.5 percent by weight of
- 25 tetrahydrocannabinols; and
- 26 (B) not less than 10 percent by weight of
- 27 cannabidiol.

| 1 | (4) "Medical use" means the ingestion by a means of |
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| 2 | administration other than by smoking of a prescribed amount of |
| 3 | low-THC cannabis by a person for whom low-THC cannabis is |
| 4 | prescribed under this chapter. |
| 5 | (5) "Smoking" means burning or igniting a substance |
| 6 | and inhaling the smoke. |
| 7 | Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THO |
| 8 | CANNABIS. (a) Only a physician qualified as provided by this |
| 9 | section may prescribe low-THC cannabis in accordance with this |
| 10 | chapter. |
| 11 | (b) A physician is qualified to prescribe low-THC cannabis |
| 12 | to a patient with intractable epilepsy if the physician: |
| 13 | (1) is licensed under this subtitle; |
| 14 | (2) dedicates a significant portion of clinical |
| 15 | practice to the evaluation and treatment of epilepsy; and |
| 16 | (3) is certified: |
| 17 | (A) by the American Board of Psychiatry and |
| 18 | <pre>Neurology in:</pre> |
| 19 | (i) epilepsy; or |
| 20 | (ii) neurology or neurology with special |
| 21 | qualification in child neurology and is otherwise qualified for the |
| 22 | examination for certification in epilepsy; or |
| 23 | (B) in neurophysiology by: |
| 24 | (i) the American Board of Psychiatry and |
| 25 | Neurology; or |
| 26 | (ii) the American Board of Clinical |
| 27 | Neurophysiology. |

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| 1 | Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A |
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| 2 | physician described by Section 169.002 may prescribe low-THC |
| 3 | cannabis to alleviate a patient's seizures if: |
| 4 | (1) the patient is a permanent resident of the state; |
| 5 | (2) the physician complies with the registration |
| 6 | requirements of Section 169.004; and |
| 7 | (3) the physician certifies to the department that: |
| 8 | (A) the patient is diagnosed with intractable |
| 9 | epilepsy; |
| 10 | (B) the physician has provided two or more |
| 11 | different treatments approved by the United States Food and Drug |
| 12 | Administration and the provided treatments have not alleviated the |
| 13 | <pre>patient's seizures;</pre> |
| 14 | (C) no other treatment options approved by the |
| 15 | United States Food and Drug Administration are available or |
| 16 | appropriate for the patient; |
| 17 | (D) the physician determines the risk of the |
| 18 | medical use of low-THC cannabis by the patient is reasonable in |
| 19 | light of the potential benefit for the patient; and |
| 20 | (E) if the patient is younger than 18 years of |
| 21 | age: |
| 22 | (i) a second physician qualified to |
| 23 | prescribe low-THC cannabis under Section 169.002 has concurred with |
| 24 | the determination under Paragraph (D); and |
| 25 | (ii) the second physician's concurrence is |
| 26 | recorded in the patient's medical record. |
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- 1 Before a physician qualified to prescribe low-THC cannabis under
- 2 Section 169.002 may prescribe or renew a prescription for low-THC
- 3 cannabis for a patient under this chapter, the physician must
- 4 register as the prescriber for that patient in the
- 5 compassionate-use registry maintained by the department under
- 6 <u>Section 487.054</u>, <u>Health and Safety Code</u>. <u>The physician's</u>
- 7 registration must indicate:
- 8 (1) the physician's name;
- 9 (2) the patient's name and date of birth;
- 10 (3) the dosage prescribed to the patient;
- 11 (4) the means of administration ordered for the
- 12 patient; and
- 13 (5) the total amount of low-THC cannabis required to
- 14 fill the patient's prescription.
- Sec. 169.005. PATIENT TREATMENT PLAN. A physician
- 16 described by Section 169.002 who prescribes low-THC cannabis for a
- 17 patient's medical use under this chapter must maintain a patient
- 18 treatment plan that indicates:
- 19 (1) the dosage, means of administration, and planned
- 20 duration of treatment for the low-THC cannabis;
- 21 (2) a plan for monitoring the patient's symptoms; and
- 22 (3) a plan for monitoring indicators of tolerance or
- 23 <u>reaction to low-THC cannabis.</u>
- SECTION 5. Section 551.004(a), Occupations Code, is amended
- 25 to read as follows:
- 26 (a) This subtitle does not apply to:
- 27 (1) a practitioner licensed by the appropriate state

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- 1 board who supplies a patient of the practitioner with a drug in a
- 2 manner authorized by state or federal law and who does not operate a
- 3 pharmacy for the retailing of prescription drugs;
- 4 (2) a member of the faculty of a college of pharmacy
- 5 recognized by the board who is a pharmacist and who performs the
- 6 pharmacist's services only for the benefit of the college;
- 7 (3) a person who procures prescription drugs for
- 8 lawful research, teaching, or testing and not for resale; [or]
- 9 (4) a home and community support services agency that
- 10 possesses a dangerous drug as authorized by Section 142.0061,
- 11 142.0062, or 142.0063, Health and Safety Code; or
- 12 (5) a dispensing organization, as defined by Section
- 13 487.001, Health and Safety Code, that cultivates, processes, and
- 14 dispenses low-THC cannabis, as authorized by Chapter 487, Health
- 15 and Safety Code, to a patient listed in the compassionate-use
- 16 registry established under that chapter.
- SECTION 6. (a) Not later than December 1, 2015, the public
- 18 safety director of the Department of Public Safety shall adopt
- 19 rules as required to implement, administer, and enforce Chapter
- 20 487, Health and Safety Code, as added by this Act, including rules
- 21 to establish the compassionate-use registry required by that
- 22 chapter.
- 23 (b) Not later than January 1, 2018, the Department of Public
- 24 Safety shall license at least three dispensing organizations in
- 25 accordance with Section 487.053, Health and Safety Code, as added
- 26 by this Act, provided at least three applicants for a license to
- 27 operate as a dispensing organization have met the requirements for

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- 1 approval provided by Subchapter C, Chapter 487, Health and Safety
- 2 Code, as added by this Act.
- 3 SECTION 7. This Act takes effect immediately if it receives
- 4 a vote of two-thirds of all the members elected to each house, as
- 5 provided by Section 39, Article III, Texas Constitution. If this
- 6 Act does not receive the vote necessary for immediate effect, this
- 7 Act takes effect September 1, 2015.