By: Campbell S.B. No. 2416

A BILL TO BE ENTITLED

1 AN ACT

- 2 relating to the medical use of low-THC cannabis and medical
- 3 research cannabis.
- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
- 5 SECTION 1. Section 481.062(a), Health and Safety Code, is
- 6 amended to read as follows:
- 7 (a) The following persons may possess a controlled
- 8 substance under this chapter without registering with the Federal
- 9 Drug Enforcement Administration:
- 10 (1) an agent or employee of a manufacturer,
- 11 distributor, analyzer, or dispenser of the controlled substance who
- 12 is registered with the Federal Drug Enforcement Administration and
- 13 acting in the usual course of business or employment;
- 14 (2) a common or contract carrier, a warehouseman, or
- 15 an employee of a carrier or warehouseman whose possession of the
- 16 controlled substance is in the usual course of business or
- 17 employment;
- 18 (3) an ultimate user or a person in possession of the
- 19 controlled substance under a lawful order of a practitioner or in
- 20 lawful possession of the controlled substance if it is listed in
- 21 Schedule V;
- 22 (4) an officer or employee of this state, another
- 23 state, a political subdivision of this state or another state, or
- 24 the United States who is lawfully engaged in the enforcement of a

- 1 law relating to a controlled substance or drug or to a customs law
- 2 and authorized to possess the controlled substance in the discharge
- 3 of the person's official duties;
- 4 (5) if the substance is tetrahydrocannabinol or one of
- 5 its derivatives:
- 6 (A) a Department of State Health Services
- 7 official, a medical school researcher, or a research program
- 8 participant possessing the substance as authorized under
- 9 Subchapter G; or
- 10 (B) a practitioner or an ultimate user possessing
- 11 the substance as a participant in a federally approved therapeutic
- 12 research program that the commissioner has reviewed and found, in
- 13 writing, to contain a medically responsible research protocol; or
- 14 (6) a dispensing organization licensed under Chapter
- 15 487 that possesses low-THC cannabis or medical research cannabis.
- SECTION 2. Section 481.111(e), Health and Safety Code, is
- 17 amended to read as follows:
- 18 (e) Sections 481.120, 481.121, 481.122, and 481.125 do not
- 19 apply to a person who engages in the acquisition, possession,
- 20 production, cultivation, delivery, or disposal of a raw material
- 21 used in or by-product created by the production or cultivation of
- 22 low-THC cannabis or medical research cannabis if the person:
- 23 (1) for an offense involving possession only of
- 24 marihuana or drug paraphernalia, is a patient for whom low-THC
- 25 cannabis or medical research cannabis is prescribed under Chapter
- 26 169, Occupations Code, or the patient's legal guardian, and the
- 27 person possesses low-THC cannabis or medical research cannabis

- 1 obtained under a valid prescription from a dispensing organization;
- 2 or
- 3 (2) is a director, manager, or employee of a
- 4 dispensing organization and the person, solely in performing the
- 5 person's regular duties at the organization, acquires, possesses,
- 6 produces, cultivates, dispenses, or disposes of:
- 7 (A) in reasonable quantities, any low-THC
- 8 cannabis or medical research cannabis or raw materials used in or
- 9 by-products created by the production or cultivation of low-THC
- 10 cannabis or medical research cannabis; or
- 11 (B) any drug paraphernalia used in the
- 12 acquisition, possession, production, cultivation, delivery, or
- 13 disposal of low-THC cannabis or medical research cannabis.
- SECTION 3. Section 481.111(f), Health and Safety Code, is
- 15 amended by adding Subdivision (3) to read as follows:
- 16 (3) "Medical research cannabis" has the meaning
- 17 <u>assigned by Section 169.001, Occupations Code.</u>
- 18 SECTION 4. Section 487.001, Health and Safety Code, is
- 19 amended by amending Subdivision (3) and adding Subdivision (5) to
- 20 read as follows:
- 21 (3) "Dispensing organization" means an organization
- 22 licensed by the department to cultivate, process, and dispense
- 23 low-THC cannabis or medical research cannabis to a patient for whom
- 24 low-THC cannabis or medical research cannabis is prescribed under
- 25 Chapter 169, Occupations Code.
- 26 (5) "Medical research cannabis" has the meaning
- 27 assigned by Section 169.001, Occupations Code.

- 1 SECTION 5. Section 487.054, Health and Safety Code, is
- 2 amended to read as follows:
- 3 Sec. 487.054. COMPASSIONATE-USE REGISTRY. (a) The
- 4 department shall establish and maintain a secure online
- 5 compassionate-use registry that contains:
- 6 (1) the name of each physician who registers as the
- 7 prescriber for a patient under Section 169.004, Occupations Code,
- 8 the name and date of birth of the patient, the dosage prescribed,
- 9 the means of administration ordered, and the total amount of
- 10 low-THC cannabis or medical research cannabis required to fill the
- 11 patient's prescription; and
- 12 (2) a record of each amount of low-THC cannabis or
- 13 medical research cannabis dispensed by a dispensing organization to
- 14 a patient under a prescription.
- 15 (b) The department shall ensure the registry:
- 16 (1) is designed to prevent more than one qualified
- 17 physician from registering as the prescriber for a single patient;
- 18 (2) is accessible to law enforcement agencies and
- 19 dispensing organizations for the purpose of verifying whether a
- 20 patient is one for whom low-THC cannabis or medical research
- 21 cannabis is prescribed and whether the patient's prescriptions have
- 22 been filled; and
- 23 (3) allows a physician qualified to prescribe low-THC
- 24 cannabis and medical research cannabis under Section 169.002,
- 25 Occupations Code, to input safety and efficacy data derived from
- 26 the treatment of patients for whom low-THC cannabis or medical
- 27 research cannabis is prescribed under Chapter 169, Occupations

- 1 Code.
- 2 SECTION 6. Section 487.102, Health and Safety Code, is
- 3 amended to read as follows:
- 4 Sec. 487.102. ELIGIBILITY FOR LICENSE. An applicant for a
- 5 license to operate as a dispensing organization is eligible for the
- 6 license if:
- 7 (1) as determined by the department, the applicant
- 8 possesses:
- 9 (A) the technical and technological ability to
- 10 cultivate and produce low-THC cannabis or medical research
- 11 cannabis;
- 12 (B) the ability to secure:
- (i) the resources and personnel necessary
- 14 to operate as a dispensing organization; and
- 15 (ii) premises reasonably located to allow
- 16 patients listed on the compassionate-use registry access to the
- 17 organization through existing infrastructure;
- 18 (C) the ability to maintain accountability for
- 19 the raw materials, the finished product, and any by-products used
- 20 or produced in the cultivation or production of low-THC cannabis or
- 21 <u>medical research cannabis</u> to prevent unlawful access to or unlawful
- 22 diversion or possession of those materials, products, or
- 23 by-products; and
- 24 (D) the financial ability to maintain operations
- 25 for not less than two years from the date of application;
- 26 (2) each director, manager, or employee of the
- 27 applicant is registered under Subchapter D; and

- 1 (3) the applicant satisfies any additional criteria
- 2 determined by the director to be necessary to safely implement this
- 3 chapter.
- 4 SECTION 7. Section 487.104(a), Health and Safety Code, is
- 5 amended to read as follows:
- 6 (a) The department shall issue or renew a license to operate
- 7 as a dispensing organization only if:
- 8 (1) the department determines the applicant meets the
- 9 eligibility requirements described by Section 487.102; and
- 10 (2) issuance or renewal of the license is necessary to
- 11 ensure reasonable statewide access to, and the availability of,
- 12 low-THC cannabis or medical research cannabis for patients
- 13 registered in the compassionate-use registry and for whom low-THC
- 14 cannabis or medical research cannabis is prescribed under Chapter
- 15 169, Occupations Code.
- 16 SECTION 8. Section 487.107, Health and Safety Code, is
- 17 amended to read as follows:
- 18 Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION.
- 19 (a) Before dispensing low-THC cannabis or medical research
- 20 cannabis to a person for whom the low-THC cannabis or medical
- 21 research cannabis is prescribed under Chapter 169, Occupations
- 22 Code, the dispensing organization must verify that the prescription
- 23 presented:
- 24 (1) is for a person listed as a patient in the
- 25 compassionate-use registry;
- 26 (2) matches the entry in the compassionate-use
- 27 registry with respect to the total amount of low-THC cannabis or

- 1 medical research cannabis required to fill the prescription; and
- 2 (3) has not previously been filled by a dispensing
- 3 organization as indicated by an entry in the compassionate-use
- 4 registry.
- 5 (b) After dispensing low-THC cannabis or medical research
- 6 cannabis to a patient for whom the low-THC cannabis or medical
- 7 <u>research cannabis</u> is prescribed under Chapter 169, Occupations
- 8 Code, the dispensing organization shall record in the
- 9 compassionate-use registry the form and quantity of low-THC
- 10 cannabis or medical research cannabis dispensed and the date and
- 11 time of dispensation.
- 12 SECTION 9. Section 487.108(c), Health and Safety Code, is
- 13 amended to read as follows:
- 14 (c) After suspending or revoking a license issued under this
- 15 chapter, the director may seize or place under seal all low-THC
- 16 cannabis or medical research cannabis and drug paraphernalia owned
- 17 or possessed by the dispensing organization. If the director
- 18 orders the revocation of the license, a disposition may not be made
- 19 of the seized or sealed low-THC cannabis or medical research
- 20 cannabis or drug paraphernalia until the time for administrative
- 21 appeal of the order has elapsed or until all appeals have been
- 22 concluded. When a revocation order becomes final, all low-THC
- 23 cannabis or medical research cannabis and drug paraphernalia may be
- 24 forfeited to the state as provided under Subchapter E, Chapter 481.
- 25 SECTION 10. Section 487.201, Health and Safety Code, is
- 26 amended to read as follows:
- Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT

- 1 LOW-THC CANNABIS OR MEDICAL RESEARCH CANNABIS. A municipality,
- 2 county, or other political subdivision may not enact, adopt, or
- 3 enforce a rule, ordinance, order, resolution, or other regulation
- 4 that prohibits the cultivation, production, dispensing, or
- 5 possession of low-THC cannabis or medical research cannabis, as
- 6 authorized by this chapter.
- 7 SECTION 11. Chapter 487, Health and Safety Code, is amended
- 8 by adding Subchapter F to read as follows:
- 9 SUBCHAPTER F. COMPASSIONATE-USE RESEARCH AND REPORTING
- 10 Sec. 487.251. COMPASSIONATE-USE INSTITUTIONAL REVIEW
- 11 BOARDS. (a) One or more institutional review boards may be
- 12 established to:
- 13 (1) evaluate and approve proposed research programs to
- 14 study the medical use of cannabis; and
- 15 (2) oversee patient treatment undertaken as part of an
- 16 approved research program, including the certification of treating
- 17 physicians and the approval of cannabis products to be prescribed
- 18 and evaluated.
- 19 <u>(b) An institutional review board must be affiliated with a</u>
- 20 dispensing organization and a:
- (1) medical school, as defined by Section 61.501,
- 22 Education Code; or
- 23 (2) hospital licensed under Chapter 241 that has at
- 24 <u>least 150 beds.</u>
- 25 (c) An institutional review board must submit written
- 26 reports that describe and assess the research findings of each
- 27 approved research program to:

- 1 (1) the department, not later than October 1 of each
- 2 year; and
- 3 (2) the legislature, not later than 90 days before
- 4 <u>each regular legislative session.</u>
- 5 (d) The Texas Medical Board may adopt rules as necessary to
- 6 implement this subchapter.
- 7 Sec. 487.252. PATIENT TREATMENT. (a) Patient treatment
- 8 provided as part of a research program under this subchapter may
- 9 only be administered by a physician certified by an institutional
- 10 review board to participate in the program. A certified physician
- 11 must remain in compliance with all applicable department and Texas
- 12 Medical Board rules and all applicable provisions of this chapter
- 13 and Chapter 169, Occupations Code.
- 14 (b) A patient participating in a research program under this
- 15 subchapter must be:
- 16 (1) a permanent resident of this state; and
- 17 (2) 21 years of age or older.
- 18 Sec. 487.253. INFORMED CONSENT. (a) Before receiving
- 19 treatment, each patient in a research program under this subchapter
- 20 must sign a written informed consent.
- 21 (b) If the patient lacks the mental capacity to provide
- 22 <u>informed consent, a parent, guardian, or conservator may provide</u>
- 23 informed consent on the patient's behalf.
- (c) An institutional review board overseeing a research
- 25 program under this subchapter may adopt a form to be used for the
- 26 informed consent required by this section.
- 27 SECTION 12. The heading to Chapter 169, Occupations Code,

- 1 is amended to read as follows:
- 2 CHAPTER 169. AUTHORITY TO PRESCRIBE LOW-THC CANNABIS OR MEDICAL
- 3 RESEARCH CANNABIS TO CERTAIN PATIENTS FOR COMPASSIONATE USE
- 4 SECTION 13. Section 169.001, Occupations Code, is amended
- 5 by amending Subdivisions (3) and (4) and adding Subdivision (3-a)
- 6 to read as follows:
- 7 (3) "Low-THC cannabis" means <u>a product derived from</u>
- 8 the plant Cannabis sativa L.[, and any part of that plant or any
- 9 compound, manufacture, salt, derivative, mixture, preparation,
- 10 resin, or oil of that plant] that contains less than one[+
- 11 $[\frac{(A)}{(A)}]$ percent by weight of
- 12 tetrahydrocannabinols[; and
- [(B) not less than 10 percent by weight of
- 14 cannabidiol].
- 15 "Medical research cannabis" means a product
- 16 derived from the plant Cannabis sativa L. that is approved by an
- 17 institutional review board for use in a research program under
- 18 Chapter 487, Health and Safety Code.
- 19 (4) "Medical use" means the ingestion by a means of
- 20 administration other than by smoking of a prescribed amount of
- 21 low-THC cannabis or medical research cannabis by a person for whom
- 22 low-THC cannabis or medical research cannabis is prescribed under
- 23 this chapter.
- SECTION 14. The heading to Section 169.002, Occupations
- 25 Code, is amended to read as follows:
- Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC
- 27 CANNABIS OR MEDICAL RESEARCH CANNABIS.

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- 1 SECTION 15. Section 169.002(a), Occupations Code, is
- 2 amended to read as follows:
- 3 (a) \underline{A} [Only a] physician <u>licensed under</u> [qualified as
- 4 provided by] this subtitle [section] may prescribe low-THC cannabis
- 5 <u>and medical research cannabis</u> in accordance with this chapter.
- 6 SECTION 16. Section 169.003, Occupations Code, is amended
- 7 to read as follows:
- 8 Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A
- 9 physician described by Section 169.002 may prescribe low-THC
- 10 cannabis [to alleviate a patient's seizures] if:
- 11 (1) the patient is a permanent resident of the state;
- 12 (2) the physician complies with the registration
- 13 requirements of Section 169.004; and
- 14 (3) the physician certifies to the department that [+
- 15 [(A) the patient is diagnosed with intractable
- 16 epilepsy;
- 17 $\left[\frac{(B)}{B}\right]$ the physician <u>has determined that</u>
- 18 [determines] the risk of the medical use of low-THC cannabis by the
- 19 patient is reasonable in light of the potential benefit for the
- 20 patient[; and
- 21 [(C) a second physician qualified to prescribe
- 22 low-THC cannabis under Section 169.002 has concurred with the
- 23 determination under Paragraph (B), and the second physician's
- 24 concurrence is recorded in the patient's medical record].
- 25 SECTION 17. Chapter 169, Occupations Code, is amended by
- 26 adding Section 169.0031 to read as follows:
- Sec. 169.0031. PRESCRIPTION OF MEDICAL RESEARCH CANNABIS.

- 1 A physician described by Section 169.002 may prescribe medical
- 2 <u>research cannabis if:</u>
- 3 (1) the prescription is for treatment approved by an
- 4 institutional review board as part of a research program under
- 5 Chapter 487, Health and Safety Code;
- 6 (2) the patient is:
- 7 (A) a permanent resident of this state; and
- 8 <u>(B) 21 years of age or older; and</u>
- 9 (3) the physician:
- 10 (A) complies with the registration requirements
- 11 of Section 169.004;
- 12 (B) is certified by an institutional review board
- 13 as a treating physician in a research program under Chapter 487,
- 14 Health and Safety Code; and
- 15 (C) certifies to the department that the
- 16 physician has determined that the risk of the medical use of medical
- 17 research cannabis by the patient is reasonable in light of the
- 18 potential benefit for the patient.
- 19 SECTION 18. Section 169.004, Occupations Code, is amended
- 20 to read as follows:
- Sec. 169.004. LOW-THC CANNABIS AND MEDICAL RESEARCH
- 22 <u>CANNABIS</u> PRESCRIBER REGISTRATION. <u>(a)</u> Before a physician
- 23 qualified to prescribe low-THC cannabis or medical research
- 24 <u>cannabis</u> under Section 169.002 may prescribe or renew a
- 25 prescription for low-THC cannabis or medical research cannabis for
- 26 a patient under this chapter, the physician must register as the
- 27 prescriber for that patient in the compassionate-use registry

- 1 maintained by the department under Section 487.054, Health and
- 2 Safety Code. The physician's registration must indicate:
- 3 (1) the physician's name;
- 4 (2) the patient's name and date of birth;
- 5 (3) the dosage prescribed to the patient;
- 6 (4) the means of administration ordered for the
- 7 patient; and
- 8 (5) the total amount of low-THC cannabis or medical
- 9 research cannabis required to fill the patient's prescription.
- 10 (b) The department may publish the name of a physician
- 11 registered under this section only if permission is expressly
- 12 granted by the physician.
- 13 SECTION 19. Section 169.005, Occupations Code, is amended
- 14 to read as follows:
- 15 Sec. 169.005. PATIENT TREATMENT PLAN. A physician
- 16 described by Section 169.002 who prescribes low-THC cannabis or
- 17 medical research cannabis for a patient's medical use under this
- 18 chapter must maintain a patient treatment plan that indicates:
- 19 (1) the dosage, means of administration, and planned
- 20 duration of treatment for the low-THC cannabis or medical research
- 21 cannabis;
- 22 (2) a plan for monitoring the patient's symptoms; and
- 23 (3) a plan for monitoring indicators of tolerance or
- 24 reaction to low-THC cannabis or medical research cannabis.
- 25 SECTION 20. Section 551.004(a), Occupations Code, is
- 26 amended to read as follows:
- 27 (a) This subtitle does not apply to:

- 1 (1) a practitioner licensed by the appropriate state
- 2 board who supplies a patient of the practitioner with a drug in a
- 3 manner authorized by state or federal law and who does not operate a
- 4 pharmacy for the retailing of prescription drugs;
- 5 (2) a member of the faculty of a college of pharmacy
- 6 recognized by the board who is a pharmacist and who performs the
- 7 pharmacist's services only for the benefit of the college;
- 8 (3) a person who procures prescription drugs for
- 9 lawful research, teaching, or testing and not for resale;
- 10 (4) a home and community support services agency that
- 11 possesses a dangerous drug as authorized by Section 142.0061,
- 12 142.0062, or 142.0063, Health and Safety Code; or
- 13 (5) a dispensing organization, as defined by Section
- 14 487.001, Health and Safety Code, that cultivates, processes, and
- 15 dispenses low-THC cannabis or medical research cannabis, as
- 16 authorized by Chapter 487, Health and Safety Code, to a patient
- 17 listed in the compassionate-use registry established under that
- 18 chapter.
- 19 SECTION 21. The following provisions of the Occupations
- 20 Code are repealed:
- 21 (1) Section 169.001(2); and
- 22 (2) Section 169.002(b).
- 23 SECTION 22. Not later than December 1, 2019, the public
- 24 safety director of the Department of Public Safety shall adopt
- 25 rules as required to implement, administer, and enforce Chapter
- 26 487, Health and Safety Code, and Chapter 169, Occupations Code, as
- 27 amended by this Act.

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- 1 SECTION 23. This Act takes effect immediately if it
- 2 receives a vote of two-thirds of all the members elected to each
- 3 house, as provided by Section 39, Article III, Texas Constitution.
- 4 If this Act does not receive the vote necessary for immediate
- 5 effect, this Act takes effect September 1, 2019.