

2019S0397-1 03/08/19

By: Campbell

S.B. No. 2416

A BILL TO BE ENTITLED

AN ACT

relating to the medical use of medical cannabis and medical research cannabis.

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

SECTION 1. Section 481.002, Health and Safety Code, Definitions is amended to read as follows:

(56) "Recommendation" means a recommendation by a physician for the use of Medical Cannabis and/or Medical Research Cannabis as defined Chapter 169, Occupations Code.SECTION 1. Section

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481.062(a), Health and Safety Code, is amended to read as follows:

(a) The following persons may possess a controlled substance under this chapter without registering with the Federal Drug Enforcement Administration:

(1) an agent or employee of a manufacturer, distributor, analyzer, or dispenser of the controlled substance who is registered with the Federal Drug Enforcement Administration

and 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;

(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

participant possessing the substance as authorized under 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 medical cannabis or medical research cannabis.

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SECTION 2. Section 481.111(e), Health and Safety Code, is amended to read as follows:

(e) Sections 481.120, 481.121, 481.122, and 481.125 do not apply to a person who engages in the acquisition, possession, production, cultivation, delivery, or disposal of a raw material used in or by-product created by the production or cultivation of medical cannabis or medical research cannabis if the person:

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(1) for an offense involving possession only of marihuana or drug paraphernalia, is a patient for whom medical cannabis or medical research cannabis is recommended under Chapter 169, Occupations Code, or the patient's legal guardian, and the

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person possesses ~~medical~~ cannabis or medical research cannabis obtained under a valid ~~recommendation~~ from a dispensing organization; or

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(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:

(A) in reasonable quantities, any ~~medical~~ cannabis or medical research cannabis or raw materials used in or by-products created by the production or cultivation of ~~medical~~ cannabis or medical research cannabis; or

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(B) any drug paraphernalia used in the acquisition, possession, production, cultivation, delivery, or disposal of ~~medical~~ cannabis or medical research cannabis.

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SECTION 3. Section 481.111(f), Health and Safety Code, is amended by adding Subdivision (3) to read as follows:

(2) "Medical cannabis" has the meaning assigned by Section 169.001, Occupations Code.

(3) "Medical research cannabis" has the meaning

assigned by Section 169.001, Occupations Code.

SECTION 4. Section 487.001, Health and Safety Code, is amended by amending Subdivision (3) and adding Subdivision (5) to read as follows:

(3) "Dispensing organization" means an organization licensed by the department to cultivate, process, and dispense medical cannabis or medical research cannabis to a patient for whom medical cannabis or medical research cannabis is recommended under Chapter 169, Occupations Code.

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(5) "Medical research cannabis" has the meaning assigned by Section 169.001, Occupations Code.

Sec. 487.053. LICENSING OF DISPENSING ORGANIZATIONS AND CANNABIS TESTING FACILITIES; REGISTRATION OF CERTAIN ASSOCIATED INDIVIDUALS.

SECTION 10. Section 487.053(a), Health and Safety Code, is amended to read as follows:

(a) The department shall:

(1) issue or renew a license under Subchapter C to operate as:

(A) a dispensing organization to each applicant who satisfies the requirements established under this chapter for licensure as a dispensing organization; and

(B) a cannabis testing facility to each applicant who satisfies the requirements established under this chapter for licensure as a cannabis testing facility. The department shall adopt rules for the administration of the cannabis testing facilities with an accreditation program which must be consistent with national accreditation standards approved by the National Environmental Laboratory Accreditation Program.; and

(2) register directors, managers, and employees under Subchapter D of each:

(A) dispensing organization; and

(B) cannabis testing facility.

SECTION 5. Section 487.054, Health and Safety Code, is amended to read as follows:

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 recommender for a patient under Section 169.004, Occupations Code, the name and date of birth of the patient, the frequency recommended, the means of administration ordered, and the total amount of medical cannabis or medical research cannabis required to fill the patient's recommendation; and

(2) a record of each amount of medical cannabis or medical research cannabis dispensed by a dispensing organization to a patient under a recommendation.

(b) The department shall ensure the registry:

(1) is designed to prevent more than one qualified physician from registering as the recommending physician 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 medical cannabis or medical research cannabis is recommended and whether the patient's recommendation have been filled; and

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(3) allows a physician qualified to ~~recommend medical~~ cannabis and medical research cannabis under Section 169.002, Occupations Code, to input safety and efficacy data derived from the treatment of patients for whom ~~medical~~ cannabis or medical research cannabis is ~~recommended~~ under Chapter 169, Occupations Code.

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SECTION 6. Section 487.102, Health and Safety Code, is amended to read as follows:

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 ~~medical~~ cannabis or medical research cannabis;

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(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 medical cannabis or medical research cannabis to prevent unlawful access to or unlawful diversion or possession of those materials, products, or by-products; and

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(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.

(4) all applications will receive priority based upon the date received by department. If previously submitted applications meet the criteria above that applicant will be

considered for a license prior to any new application.

SECTION 7. Section 487.104(a), Health and Safety Code, is amended to read as follows:

(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, medical cannabis or medical research cannabis for patients registered in the compassionate-use registry and for whom Medical cannabis or medical research cannabis is recommended under Chapter 169, Occupations Code.

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SECTION 8. Section 487.107, Health and Safety Code, is amended to read as follows:

Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION.

(a) Before dispensing medical cannabis or medical research cannabis to a person for whom the medical cannabis or medical research cannabis is recommended under Chapter 169, Occupations

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Code, the dispensing organization must verify that the recommendation presented:

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

(2) matches the entry in the compassionate-use registry with respect to the total amount of medical cannabis or medical research cannabis required to fill the recommendation; and

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(3) has not previously been filled by a dispensing organization as indicated by an entry in the compassionate-use registry.

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

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SECTION 9. Section 487.108(c), Health and Safety Code, is amended to read as follows:

(c) After suspending or revoking a license issued under this chapter, the director may seize or place under seal all medical cannabis or medical research cannabis and drug paraphernalia owned or possessed by the dispensing organization. If the director orders the revocation of the license, a disposition may not be made of the seized or sealed medical cannabis or medical research 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 medical cannabis or medical research cannabis and drug paraphernalia may be forfeited to the state as provided under Subchapter E, Chapter 481.

SECTION 10. Section 487.201, Health and Safety Code, is amended to read as follows:

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT MEDICAL CANNABIS OR MEDICAL RESEARCH 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

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possession of medical cannabis or medical research cannabis, as authorized by this chapter.

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SECTION 11. Chapter 487, Health and Safety Code, is amended by adding Subchapter F to read as follows:

SUBCHAPTER F. COMPASSIONATE-USE RESEARCH AND REPORTING

Sec. 487.251. COMPASSIONATE-USE INSTITUTIONAL REVIEW BOARDS. (a) One or more institutional review boards may be established to:

(1) evaluate and approve proposed research programs to study the medical use of cannabis; and

(2) oversee patient treatment undertaken as part of an approved research program, including the certification of treating physicians and the approval of cannabis products to be recommended and evaluated.

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(b) An institutional review board must be affiliated with a dispensing organization and a:

(1) medical school, as defined by Section 61.501, Education Code; or

(2) hospital licensed under Chapter 241 that has at

least 150 beds.

(c) An institutional review board must submit written reports that describe and assess the research findings of each approved research program to:

(1) the department, not later than October 1 of each year; and

(2) the legislature, not later than 90 days before each regular legislative session.

(d) The Texas Medical Board may adopt rules as necessary to implement this subchapter.

Sec. 487.252. PATIENT TREATMENT. (a) Patient treatment provided as part of a research program under this subchapter may only be administered by a physician certified by an institutional review board to participate in the program. A certified physician must remain in compliance with all applicable department and Texas Medical Board rules and all applicable provisions of this chapter and Chapter 169, Occupations Code.

(b) A patient participating in a research program under this subchapter must be:

(1) a permanent resident of this state; and

(2) 21 years of age or older.

Sec. 487.253. INFORMED CONSENT. (a) Before receiving treatment, each patient in a research program under this subchapter must sign a written informed consent.

(b) If the patient lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

(c) An institutional review board overseeing a research program under this subchapter may adopt a form to be used for the informed consent required by this section.

SECTION 12. The heading to Chapter 169, Occupations Code, is amended to read as follows:

CHAPTER 169. AUTHORITY TO ~~RECOMMEND MEDICAL~~ CANNABIS OR MEDICAL ~~RESEARCH CANNABIS~~ TO CERTAIN PATIENTS FOR COMPASSIONATE USE

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SECTION 13. Section 169.001, Occupations Code, is amended by amending Subdivisions (3) and (4) and adding Subdivision (3-a) to read as follows:

(3) "~~medical~~ cannabis" means a product derived from

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the plant Cannabis sativa L. [~~and any part of that plant or any compound, manufacture, salt, derivative, mixture, preparation, resin, or oil of that plant,~~

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(B) ~~not less than 10 percent by weight of cannabidiol,~~

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(3-a) "Medical research cannabis" means a product derived from the plant Cannabis sativa L. that is approved by an institutional review board for use in a research program under Chapter 487, Health and Safety Code.

(4) "Medical use" means the ingestion by a means of administration ~~as recommended by a physician under this chapter for the use of,~~ medical cannabis or medical research cannabis by a person for whom ~~medical cannabis or medical research cannabis is recommended,~~ under this chapter.

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SECTION 14. The heading to Section 169.002, Occupations Code, is amended to read as follows:

Sec. 169.002. PHYSICIAN QUALIFIED TO ~~RECOMMEND,~~ MEDICAL CANNABIS OR MEDICAL RESEARCH CANNABIS.

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SECTION 15. Section 169.002(a), Occupations Code, is amended



to read as follows:

(a) A ~~[Only a]~~ physician licensed under ~~[qualified as provided by]~~ this subtitle ~~[section]~~ may recommend ~~medical~~ cannabis and medical research cannabis in accordance with this chapter.

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SECTION 16. Section 169.003, Occupations Code, is amended to read as follows:

Sec. 169.003. RECOMMENDATION ~~OF~~ MEDICAL CANNABIS. A physician described by Section 169.002 may recommend ~~medical~~ cannabis ~~[to alleviate a patient's seizures]~~ if:

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- (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 determined that ~~[determines]~~ the risk of the medical use of medical cannabis by the patient is reasonable in light of the potential benefit for

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the patient[ ~~and~~

~~[(C) a second physician qualified to prescribe  
 Medical 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].~~

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SECTION 17. Chapter 169, Occupations Code, is amended by adding Section 169.0031 to read as follows:

Sec. 169.0031. RECOMMENDATION OF MEDICAL RESEARCH CANNABIS.

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A physician described by Section 169.002 may recommendation  
 medical research cannabis if:

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(1) the recommendation is for treatment approved by an  
 institutional review board as part of a research program under  
 Chapter 487, Health and Safety Code;

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(2) the patient is:

(A) a permanent resident of this state; and

(B) 21 years of age or older; and

(3) the physician:

(A) complies with the registration requirements of  
 Section 169.004;

(B) is certified by an institutional review board as a treating physician in a research program under Chapter 487, Health and Safety Code; and

(C) certifies to the department that the physician has determined that the risk of the medical use of medical research cannabis by the patient is reasonable in light of the potential benefit for the patient.

SECTION 18. Section 169.004, Occupations Code, is amended to read as follows:

Sec. 169.004. ~~MEDICAL CANNABIS AND MEDICAL RESEARCH CANNABIS RECOMMENDER~~ REGISTRATION. (a) Before a physician qualified to ~~recommend Medical~~ cannabis or medical research cannabis under Section 169.002 may ~~recommend~~ or renew a ~~recommendation~~ for ~~Medical~~ cannabis or medical research cannabis for a patient under this chapter, the physician must register as ~~the recommender~~ 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;

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(2) the patient's name and date of birth; and  
(3) the means of administration recommended for the  
patient;

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(b) The department may publish the name of a physician registered under this section only if permission is expressly granted by the physician.

SECTION 19. Section 169.005, Occupations Code, is amended to read as follows:

Sec. 169.005. PATIENT TREATMENT PLAN. A physician described by Section 169.002 who recommends Medical cannabis or medical research cannabis for a patient's medical use under this chapter must maintain a patient treatment plan that indicates:

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- (1) means of administration, and planned duration of treatment for the Medical cannabis or medical research cannabis;
- (2) a plan for monitoring the patient's symptoms; and
- (3) a plan for monitoring indicators of tolerance or reaction to medical cannabis or medical research cannabis.

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SECTION 20. 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;

(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;

(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 ~~medical~~ cannabis or medical research cannabis, as authorized by Chapter 487, Health and Safety Code, to a patient listed in the compassionate-use registry established under that chapter.

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SECTION 21. The following provisions of the Occupations Code are repealed:

- (1) Section 169.001(2); and
- (2) Section 169.002(b).

SECTION 22. Not later than December 1, 2019, 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, and Chapter 169, Occupations Code, as amended by this Act.

SECTION 23. 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, 2019.