Texas House Bill 1365 by Rep. Eddie Lucio III

Expanding Low-THC Cannabis Access and
Establishing Cannabis Research/Review Board

Currently, the Texas Compassionate Use Program (T.CUP) allows legal access to low-THC cannabis and cannabis products for those with intractable epilepsy. Rep. Eddie Lucio III's HB 1365 expands this legal access and establishes a Cannabis Research Program and Review Board. Among other things, the review board may add qualifying conditions and determine allowable dosages, including THC content.

Patient Access to Low-THC Cannabis

Under new rules, to participate in T.CUP, a patient must have a debilitating medical condition, a prescription from a registered physician, and confirmation from a second registered physician.

Patients may possess a 30-day supply of cannabis or cannabis products as determined by their physician and documented in the Compassionate Use Registry. Cannabis medicine may not be smoked, but patients may utilize vaporization as a method of administration as well as oils and infused products.

Debilitating medical conditions:

- Cancer
- Autism
- Post-traumatic stress disorder
- Alzheimer's disease
- Parkinson's disease
- Huntington's disease
- Amyotrophic lateral sclerosis
- Tourette syndrome
- Crohn's disease
- Ulcerative colitis
- Muscular dystrophy
- Multiple sclerosis

Or any medical condition (or treatment) that produces:

- endocannabinoid deficiency syndrome
- cachexia or wasting syndrome
- neuropathy, neuropathic, somatic, or severe intractable pain
- severe nausea
- seizures, including those characteristic of epilepsy
- severe and persistent muscle spasms, including those characteristic of multiple sclerosis
- tic disorders

Adding Access to All Cannabinoids: The review board will determine the formulations and dosages, including ratios of cannabinoids, that are medically appropriate for patients with particular debilitating medical conditions.

Referring Patient to Research Program: Physician may refer a patient to a research program if the patient has a condition, symptom, or side effects that may be alleviated by medical use of cannabis and the risk is reasonable in light of the potential benefit for the patient.

Patient, Parent, and Caregiver Protections:

- Not be subject to arrest, prosecution, or penalty in any manner, or denial of any right or privilege, including any civil penalty or disciplinary action by a court or occupational or professional licensing.
- No denial of parental rights.
- No prosecution for paraphernalia.
- Students cannot be subject to any form of discipline solely because of possession or use of their medicine.

Designating a Caregiver: Registered patients may designate one caregiver (and an alternate) with DPS. Caregivers may not have a felony conviction relating to a controlled substance.

A person may only be caregiver/alternate caregiver for one patient, unless: each patient is related to the caregiver within the fourth degree of consanguinity or affinity OR the caregiver is employed by a home health care agency or other service and provides assistance to multiple patients as a part of the caregiver's job duties.

Compassionate Use Registry (Physician Participation)

Physician must comply with registration requirements and certify there is a bona fide physician-patient relationship, patient is diagnosed with a debilitating medical condition, potential benefits outweigh the risks, and physician has obtained the proper medical knowledge required.

"Prescription" means an order by a physician, provided on a secure online form that specifies the date of order; name/DOB of patient; the dosage, any cannabinoid ratios, and quantity prescribed to a patient; directions for the use and means of administration; an amount of cannabis needed by the patient for a 30-day period. Adverse events must be reported in registry.

A physician may prescribe cannabis for a patient with a debilitating medical condition, provided that the physician has obtained the proper medical knowledge concerning medical use as a treatment for a patient's particular debilitating medical condition through a course of instruction provided for that purpose, continuing medical education relating to medical use, or self-study. The review board may establish training criteria for the qualification of a physician.

Physician Protections: Physicians may not be denied any right or privilege or be subject to disciplinary action solely for making a written or oral statement that, in the physician's professional opinion, the potential benefits of the use of cannabis would likely outweigh the health risks; or participating in research programs. The department may publish the name of a registered physician only with physician's express permission. The physician's name is confidential and not subject to disclosure.

Consumer Protections

Independent third-party testing available through licensed laboratories. Upon request from the department, dispensing organization must provide a sample of their product suitable for testing.

DPS will institute labeling requirements for cannabis products, including disclosure of cannabinoid and terpene quantities.

With consultation from the Cannabis Therapeutic Review Board, DPS will monitor the safety and efficacy of cannabis products, including requiring accurate reporting to consumers by testing facilities, and providing random testing by the department to ensure compliance. DPS will collect data from dispensing organizations, cannabis research organizations, cannabis testing facilities, and health care providers as necessary to enable the department to monitor the safety and efficacy of products.

Cannabis Therapeutic Research Program and Review Board

The Cannabis Therapeutic Research Program and Review Board works in consultation with the Department of Public Safety, but is regulated by the Health and Human Services Commission.

The review board will encourage multiple research goals, including:

- Objective scientific research into the safety and efficacy of low-THC cannabis;
- Developing medical guidelines for the appropriate administration of low-THC cannabis, to assist physicians and patients in evaluating the risks and benefits of low-THC cannabis, and to provide a scientific basis for future policies;
- Developing quality control, purity, and labeling standards for low-THC cannabis;
- Developing best practices for the safe and efficient cultivation of low THC cannabis; and
- Analysis of genetic and healing properties of different varieties of cannabis.

The review board is made up of twelve members appointed by the governor for staggered 6 year terms, including a physicians certified by each of the following:

1. American Board of Ophthalmology;
2. American Board of Internal Medicine and certified in the subspecialty of medical oncology;
3. American Board of Psychiatry;
4. American Board of Surgery;
5. American Board of Radiology;
6. American Board of Psychiatry and Neurology (2);
7. American Board of Family Medicine;
8. American Osteopathic Association; and

- a licensed physician specializing in pain management certified by the American Board of Anesthesiology, the American Board of Psychiatry, the American Board of Neurology, or the American Board of Physical Medicine and Rehabilitation;
- a licensed advanced practice registered nurse specializing in palliative care certified by the Hospice and Palliative Credentialing Center or a licensed physician specializing in palliative care certified by a member board of the American Board of Medical Specialties, the American Osteopathic Association, or the Hospice Medical Director Certification Board; and
- a licensed attorney with experience in law pertaining to the practice of medicine;

Research programs may be conducted with a medical school, hospital, or general academic teaching institution, and may investigate the safety and efficacy of cannabis and other health outcomes. Cannabis for research purposes can acquired from T.CUP license holders or by contracting with NIDA in accordance with NIDA, FDA, and DEA regulations.

Physician may refer a patient to a research program if the person has a condition, symptom, or side-effect that may be alleviated by medical use of low-THC cannabis and the risk of the medical use of low-THC cannabis is reasonable in light of the potential benefit for the patient.

The review board may accept donations for research and provide grants for research into low-THC cannabis use, health outcomes, and scientific public education outreach to educate youth on the risks of using cannabis for nonmedical purposes or without the supervision of a health care provider.

Duties/Responsibilities:

- Review research proposals, approve research programs, and conduct periodic reviews of the research and participants. Research programs will be approved based on which are most suitable for the therapy and research purposes of the program.
- Require written reports that describe and assess the research findings by each approved research program, including research findings relating to the safety and efficacy of cannabis. Submit a report on the status and findings of the research programs by Oct. 1 of each year.
- Determine the formulations and dosages, including ratios of cannabinoids, that are medically appropriate for patients with particular debilitating medical conditions.
- Add qualifying conditions for T.CUP after reviewing published, peer-reviewed medical literature and research results that indicate likely benefit of medical use in the treatment or alleviation of a medical condition or symptom outweighs any likely harm to patients.
- Track adverse effects of cannabis use as reported by registered physicians. Report on the quality, diversity, and availability of cannabis in the state.
- Conduct a continuing study of the laws relating to cannabis to facilitate statewide access to safe and effective cannabis and report the board's findings and recommendations to the legislature at least 90 days before each legislative session.

Optional Powers:

- Establish training criteria for the qualification of a physician.
- Create and appoint one or more advisory committees composed of patients, law enforcement officers, medical professionals, and other persons who are knowledgeable about cannabis cultivation, processing, and regulation.

Cannabis Organization Licensing

There will now be three types of licensed cannabis organizations: dispensing (included cultivation and processing), research, and testing. Licenses will be issued to ensure reasonable statewide access to cannabis for qualifying patients. DPS must issue a minimum of nine additional dispensing licenses by Sept. 1, 2019. (Licenses/registrations issued previously are grandfathered in and expire as contracted.)

A dispensing organization may operate three additional retail dispensing locations under a single license. If the department determines that additional locations are necessary to meet patient access needs, then a licensee may operate more than four dispensing locations. (Additional application fees may apply.)

Reasonable licensing fees will be used to cover costs for the administration of T.CUP, the research program/review board, and testing and quality control fund for the cost of equipment to test cannabis, cannabis products, and other substances for the purpose of assisting law enforcement.

Important Dates

September 1, 2019 - New law goes into effect, including the issuance of at least a total of 12 dispensing licenses, provided at least 12 applicants meet requirements.

December 1, 2019 - New Rules from DPS

March 1, 2020 - DPS shall begin licensing research organizations and testing facilities.