

BILL ANALYSIS

Senate Research Center

H.B. 1535
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State Affairs
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Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

H.B. 1535 provides necessary improvements to the Texas Compassionate Use Program (TCUP) so patients with debilitating medical conditions may access low-THC cannabis products for symptom treatment and relief.

This bill extends the program to:

1. All cancer patients. Currently, only terminal cancer patients have access;
2. Patients with chronic pain, instead of getting a prescription for opioids;
3. Patients with post-traumatic stress disorder (PTSD); and
4. Patients with "debilitating medical conditions" as defined by the Department of State Health Services (DSHS).

The bill authorizes the establishment of one or more compassionate-use institutional review boards to do the following:

1. Evaluate and approve proposed research programs to study the medical use of low-THC cannabis in treating a medical condition designated by applicable rule of the executive commissioner of the Health and Human Services Commission (HHSC); and
2. Oversee patient treatment undertaken as part of an approved research program, including the certification of treating physicians.

Finally, the bill increases the low-THC percentage for medicinal cannabis from 0.5 percent to 5 percent.

H.B. 1535 amends current law relating to the medical use of low-THC cannabis by patients with certain medical conditions and the establishment of compassionate-use institutional review boards to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in the treatment of certain patients.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 (Section 487.252, Health and Safety Code) of this bill.

Rulemaking authority is expressly granted to the Texas Medical Board in SECTION 1 (Section 487.252, Health and Safety Code) of this bill.

Rulemaking authority is expressly granted to the Department of State Health Services in SECTION 4 (Section 169.003, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 487, Health and Safety Code, by adding Subchapter F, as follows:

SUBCHAPTER F. COMPASSIONATE-USE RESEARCH AND REPORTING

Sec. 487.251. DEFINITIONS. Defines "executive commissioner" and "institutional review board."

Sec. 487.252. RULES. (a) Requires the executive commissioner of the Health and Human Services Commission (executive commissioner), except as otherwise provided by Subsection (b), to adopt all necessary rules to implement this subchapter, including rules designating the medical conditions for which a patient is authorized to be treated with low-THC cannabis as part of an approved research program conducted under this subchapter.

(b) Authorizes the Texas Medical Board (TMB) to adopt rules regarding the certification of a physician by a compassionate-use institutional review board established under Section 487.253 (board).

Sec. 487.253. COMPASSIONATE-USE INSTITUTIONAL REVIEW BOARDS. (a) Authorizes one or more boards to be established to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in treating a medical condition designated by rule of the executive commissioner under Section 487.252(a), and to oversee patient treatment undertaken as part of an approved research program, including the certification of treating physicians.

(b) Requires a board to be affiliated with a dispensing organization and meet one of the following conditions:

(1) be affiliated with a medical school, as defined by Section 61.501 (Definitions), Education Code;

(2) be affiliated with a hospital licensed under Chapter 241 (Hospitals) that has at least 150 beds;

(3) be accredited by the Association for the Accreditation of Human Research Protection Programs;

(4) be registered by the United States Department of Health and Human Services, Office for Human Research Protections, in accordance with 21 C.F.R. Part 56; or

(5) be accredited by a national accreditation organization acceptable to TMB.

Sec. 487.254. REPORTS BY INSTITUTIONAL REVIEW BOARDS. Requires each board to submit written reports that describe and assess the research findings of each approved research program to the Health and Human Services Commission, not later than October 1 of each year; and to the legislature, not later than October 1 of each even-numbered year.

Sec. 487.255. PATIENT TREATMENT. (a) Authorizes patient treatment provided as part of an approved research program under this subchapter to be administered only by a physician certified by a board to participate in the program.

(b) Requires a patient participating in a research program under this subchapter to be a permanent resident of this state.

Sec. 487.256. INFORMED CONSENT. (a) Requires each patient, before receiving treatment under an approved research program, to sign a written informed consent form.

(b) Authorizes a parent, guardian, or conservator, if the patient is a minor or lacks the mental capacity to provide informed consent, to provide informed consent on the patient's behalf.

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

SECTION 2. Amends Section 169.001(3), Occupations Code, to redefine "low-THC cannabis" to mean 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 that contains not more than five percent, rather than 0.5 percent, by weight of tetrahydrocannabinols.

SECTION 3. Amends Section 169.002, Occupations Code, by adding Subsection (c), as follows:

(c) Provides that a physician is qualified to prescribe low-THC cannabis for the treatment of a patient with a medical condition approved by rule of the executive commissioner for treatment in an approved research program conducted under Subchapter F, Chapter 487 (Texas Compassionate-Use Act), Health and Safety Code, if the physician is licensed under Subtitle B (Physicians), and is certified by a board created under Section 487.253, Health and Safety Code, that oversees patient treatment undertaken as part of that approved research program.

SECTION 4. Amends Section 169.003, Occupations Code, as follows:

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. (a) Creates this subsection from existing text. Authorizes a physician described by Section 169.002 (Physician Qualified to Prescribe Low-THC Cannabis to Patients With Certain Medical Conditions) to prescribe low-THC cannabis to a patient if:

(1) and (2) makes no changes to these subdivisions;

(3) the physician certifies to the Department of Public Safety of the State of Texas (DPS) that:

(A) the patient is diagnosed with:

(i)-(vi) makes no changes to these subparagraphs;

(vii) cancer, rather than terminal cancer;

(viii) makes no changes to this subparagraph;

(ix) a condition that causes chronic pain, for which a physician would otherwise prescribe an opioid;

(x) post-traumatic stress disorder;

(xi) a medical condition that is approved for a research program under Subchapter F, Chapter 487, Health and Safety Code, and for which the patient is receiving treatment under that program; or

(xii) a debilitating medical condition designated by the Department of State Health Services (DSHS) under Subsection (b); and

(B) makes no changes to this paragraph.

(b) Authorizes DSHS by rule to designate debilitating medical conditions for which a physician is authorized to prescribe low-THC cannabis under this section.

SECTION 5. Repealer: Section 169.001(6) (relating to the definition of "terminal cancer"), Occupations Code.

SECTION 6. (a) Requires the executive commissioner, not later than December 1, 2021, to adopt rules as necessary under Section 487.252, Health and Safety Code, as added by this Act.

(b) Requires the public safety director of DPS, not later than December 1, 2021, to adopt or amend DPS rules regarding the cultivation, processing, and dispensing of low-THC cannabis by a licensed dispensing organization under Chapter 487, Health and Safety Code.

SECTION 7. Effective date: September 1, 2021.