

House Bill 1535
Senate Amendments
Section-by-Section Analysis

HOUSE VERSION

SECTION 1. 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. DEFINITIONS. In this subchapter:

(1) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(2) "Institutional review board" means a compassionate-use institutional review board established under Section 487.253.

Sec. 487.252. RULES. (a) Except as otherwise provided by Subsection (b), the executive commissioner shall adopt all necessary rules to implement this subchapter, including rules designating the medical conditions for which a patient may be treated with low-THC cannabis as part of an approved research program conducted under this subchapter.

(b) The Texas Medical Board may adopt rules regarding the certification of a physician by an institutional review board.

Sec. 487.253. COMPASSIONATE-USE INSTITUTIONAL REVIEW BOARDS. (a) One or more compassionate-use institutional review boards may be established to:

(1) 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

(2) oversee patient treatment undertaken as part of an approved research program, including the certification of treating physicians.

(b) An institutional review board must be affiliated with a dispensing organization and meet one of the following conditions:

(1) be affiliated with a medical school, as defined by Section

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SECTION 1. Same as House version.

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61.501, Education Code;

(2) be affiliated with a hospital licensed under Chapter 241 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 the Texas Medical Board.

Sec. 487.254. REPORTS BY INSTITUTIONAL REVIEW BOARDS. Each institutional review board shall submit written reports that describe and assess the research findings of each approved research program to:

(1) the Health and Human Services Commission, not later than October 1 of each year; and

(2) the legislature, not later than October 1 of each even-numbered year.

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

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

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

(b) If the patient is a minor or 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

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program under this subchapter may adopt a form to be used for the informed consent required by this section.

SECTION 2. Section 169.001(3), Occupations Code, is amended to read as follows:

(3) "Low-THC cannabis" means 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 [0.5] percent by weight of tetrahydrocannabinols.

SECTION 3. Section 169.002, Occupations Code, is amended by adding Subsection (c) to read as follows:

(c) 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 of the Health and Human Services Commission for treatment in an approved research program conducted under Subchapter F, Chapter 487, Health and Safety Code, if the physician is:

(1) licensed under this subtitle; and

(2) certified by a compassionate-use institutional review board created under Section 487.253, Health and Safety Code, that oversees patient treatment undertaken as part of that approved research program.

SECTION 4. Section 169.003, Occupations Code, is amended to read as follows:

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS.
(a) A physician described by Section 169.002 may prescribe

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SECTION 2. Section 169.001(3), Occupations Code, is amended to read as follows:

(3) "Low-THC cannabis" means 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 one [0.5] percent by weight of tetrahydrocannabinols.

SECTION 3. Same as House version.

SECTION 4. Section 169.003, Occupations Code, is amended to read as follows:

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS.
A physician described by Section 169.002 may prescribe low-

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low-THC cannabis to a patient if:

- (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:
 - (i) epilepsy;
 - (ii) a seizure disorder;
 - (iii) multiple sclerosis;
 - (iv) spasticity;
 - (v) amyotrophic lateral sclerosis;
 - (vi) autism;
 - (vii) ~~terminal~~ cancer; ~~or~~
 - (viii) an incurable neurodegenerative disease;
 - (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 under Subsection (b);
 - (B) the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient.
- (b) The Department of State Health Services by rule may designate debilitating medical conditions for which a physician may prescribe low-THC cannabis under this section.

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THC cannabis to a patient if:

- (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:
 - (i) epilepsy;
 - (ii) a seizure disorder;
 - (iii) multiple sclerosis;
 - (iv) spasticity;
 - (v) amyotrophic lateral sclerosis;
 - (vi) autism;
 - (vii) ~~terminal~~ cancer; ~~or~~
 - (viii) an incurable neurodegenerative disease;
 - (ix) post-traumatic stress disorder; or
 - (x) 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; and
- (B) the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient.

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SECTION 5. Section 169.001(6), Occupations Code, is repealed.

SECTION 6. (a) Not later than December 1, 2021, the executive commissioner of the Health and Human Services Commission shall adopt rules as necessary under Section 487.252, Health and Safety Code, as added by this Act.

(b) Not later than December 1, 2021, the public safety director of the Department of Public Safety shall adopt or amend department 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. This Act takes effect September 1, 2021.

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SECTION 5. Same as House version.

SECTION 6. Same as House version.

SECTION 7. Same as House version.

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