

1 AN ACT

2 relating to the medical use of low-THC cannabis by patients with
3 certain medical conditions and the establishment of
4 compassionate-use institutional review boards to evaluate and
5 approve proposed research programs to study the medical use of
6 low-THC cannabis in the treatment of certain patients.

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

8 SECTION 1. Chapter 487, Health and Safety Code, is amended
9 by adding Subchapter F to read as follows:

10 SUBCHAPTER F. COMPASSIONATE-USE RESEARCH AND REPORTING

11 Sec. 487.251. DEFINITIONS. In this subchapter:

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

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

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

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

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

4 (1) evaluate and approve proposed research programs to
5 study the medical use of low-THC cannabis in treating a medical
6 condition designated by rule of the executive commissioner under
7 Section 487.252(a); and

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

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

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

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

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

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

22 (5) be accredited by a national accreditation
23 organization acceptable to the Texas Medical Board.

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

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

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

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

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

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

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

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

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

22 (3) "Low-THC cannabis" means the plant Cannabis sativa
23 L., and any part of that plant or any compound, manufacture, salt,
24 derivative, mixture, preparation, resin, or oil of that plant that
25 contains not more than one [~~0.5~~] percent by weight of
26 tetrahydrocannabinols.

27 SECTION 3. Section 169.002, Occupations Code, is amended by

1 adding Subsection (c) to read as follows:

2 (c) A physician is qualified to prescribe low-THC cannabis
3 for the treatment of a patient with a medical condition approved by
4 rule of the executive commissioner of the Health and Human Services
5 Commission for treatment in an approved research program conducted
6 under Subchapter F, Chapter 487, Health and Safety Code, if the
7 physician is:

8 (1) licensed under this subtitle; and

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

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

15 Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A
16 physician described by Section 169.002 may prescribe low-THC
17 cannabis to a patient if:

18 (1) the patient is a permanent resident of the state;

19 (2) the physician complies with the registration
20 requirements of Section 169.004; and

21 (3) the physician certifies to the department that:

22 (A) the patient is diagnosed with:

23 (i) epilepsy;

24 (ii) a seizure disorder;

25 (iii) multiple sclerosis;

26 (iv) spasticity;

27 (v) amyotrophic lateral sclerosis;

- 1 (vi) autism;
- 2 (vii) [~~terminal~~] cancer; [~~or~~]
- 3 (viii) an incurable neurodegenerative
- 4 disease;
- 5 (ix) post-traumatic stress disorder; or
- 6 (x) a medical condition that is approved
- 7 for a research program under Subchapter F, Chapter 487, Health and
- 8 Safety Code, and for which the patient is receiving treatment under
- 9 that program; and

10 (B) the physician determines the risk of the
11 medical use of low-THC cannabis by the patient is reasonable in
12 light of the potential benefit for the patient.

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

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

19 (b) Not later than December 1, 2021, the public safety
20 director of the Department of Public Safety shall adopt or amend
21 department rules regarding the cultivation, processing, and
22 dispensing of low-THC cannabis by a licensed dispensing
23 organization under Chapter 487, Health and Safety Code.

24 SECTION 7. This Act takes effect September 1, 2021.

President of the Senate

Speaker of the House

I certify that H.B. No. 1535 was passed by the House on April 29, 2021, by the following vote: Yeas 134, Nays 12, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 1535 on May 28, 2021, by the following vote: Yeas 119, Nays 25, 1 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 1535 was passed by the Senate, with amendments, on May 25, 2021, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

Governor