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et al.

H.B. No. 1535

A BILL TO BE ENTITLED

AN ACT

1
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, Occupations Code, is amended by
21 amending Subdivision (3) and adding Subdivision (7) to read as
22 follows:

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

1 (7) "Veteran" means a person who has served in:

2 (A) the army, navy, air force, coast guard, or
3 marine corps of the United States;

4 (B) the state military forces as defined by
5 Section 431.001, Government Code; or

6 (C) an auxiliary service of one of those branches
7 of the armed forces.

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

10 (c) A physician is qualified to prescribe low-THC cannabis
11 for the treatment of a patient with a medical condition approved by
12 rule of the executive commissioner of the Health and Human Services
13 Commission for treatment in an approved research program conducted
14 under Subchapter F, Chapter 487, Health and Safety Code, if the
15 physician is:

16 (1) licensed under this subtitle; and

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

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

23 Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. (a) A
24 physician described by Section 169.002 may prescribe low-THC
25 cannabis to a patient if:

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

27 (2) the physician complies with the registration

1 requirements of Section 169.004; and

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

3 (A) the patient is diagnosed with:

4 (i) epilepsy;

5 (ii) a seizure disorder;

6 (iii) multiple sclerosis;

7 (iv) spasticity;

8 (v) amyotrophic lateral sclerosis;

9 (vi) autism;

10 (vii) ~~[terminal]~~ cancer; ~~[or]~~

11 (viii) an incurable neurodegenerative
12 disease;

13 (ix) a condition that causes acute or
14 chronic pain, for which a physician would otherwise prescribe an
15 opioid;

16 (x) post-traumatic stress disorder and is a
17 veteran;

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

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

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

1 (b) The Department of State Health Services by rule may
2 designate debilitating medical conditions for which a physician may
3 prescribe low-THC cannabis under this section.

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

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

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

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