

By: \_\_\_\_\_ .B. No. \_\_\_\_\_

Substitute the following for \_\_\_\_\_ .B. No. \_\_\_\_\_:

By: \_\_\_\_\_ C.S. \_\_\_\_\_ .B. No. \_\_\_\_\_

A BILL TO BE ENTITLED

1 AN ACT

2 relating to the medical use of low-THC cannabis by patients with  
3 certain medical conditions and the establishment of compassionate-  
4 use institutional review boards to evaluate and approve proposed  
5 research programs to study the medical use of low-THC cannabis in  
6 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 compassionate-  
15 use institutional review board established under Section 487.253.

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

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

24 Sec. 487.253. COMPASSIONATE-USE INSTITUTIONAL REVIEW

1 BOARDS. (a) One or more compassionate-use institutional review  
2 boards may be established to:

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

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

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

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

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

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

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

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

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

27 (1) the Health and Human Services Commission, not later

1 than October 1 of each year; and

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

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

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

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

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

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

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

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

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

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

7            (1) licensed under this subtitle; and

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

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

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

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

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

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

21                    (A) the patient is diagnosed with:

22                            (i) epilepsy;

23                            (ii) a seizure disorder;

24                            (iii) multiple sclerosis;

25                            (iv) spasticity;

26                            (v) amyotrophic lateral sclerosis;

27                            (vi) autism;

1 (vii) [~~terminal~~] cancer; [~~or~~]  
2 (viii) an incurable neurodegenerative  
3 disease;

4 (ix) post-traumatic stress disorder; or

5 (x) a medical condition that is approved for  
6 a research program under Subchapter F, Chapter 487, Health and  
7 Safety Code, and for which the patient is receiving treatment under  
8 that program; and

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

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

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

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

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