

1-1 By: Klick, et al. (Senate Sponsor - Schwertner) H.B. No. 1535  
1-2 (In the Senate - Received from the House May 3, 2021;  
1-3 May 20, 2021, read first time and referred to Committee on State  
1-4 Affairs; May 24, 2021, reported adversely, with favorable  
1-5 Committee Substitute by the following vote: Yeas 9, Nays 0;  
1-6 May 24, 2021, sent to printer.)

1-7 COMMITTEE VOTE

	Yea	Nay	Absent	PNV
1-8				
1-9	<u>X</u>			
1-10	<u>X</u>			
1-11	<u>X</u>			
1-12	<u>X</u>			
1-13	<u>X</u>			
1-14	<u>X</u>			
1-15	<u>X</u>			
1-16	<u>X</u>			
1-17	<u>X</u>			

1-18 COMMITTEE SUBSTITUTE FOR H.B. No. 1535 By: Schwertner

1-19 A BILL TO BE ENTITLED  
1-20 AN ACT

1-21 relating to the medical use of low-THC cannabis by patients with  
1-22 certain medical conditions and the establishment of  
1-23 compassionate-use institutional review boards to evaluate and  
1-24 approve proposed research programs to study the medical use of  
1-25 low-THC cannabis in the treatment of certain patients.

1-26 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-27 SECTION 1. Chapter 487, Health and Safety Code, is amended  
1-28 by adding Subchapter F to read as follows:

1-29 SUBCHAPTER F. COMPASSIONATE-USE RESEARCH AND REPORTING

1-30 Sec. 487.251. DEFINITIONS. In this subchapter:

1-31 (1) "Executive commissioner" means the executive  
1-32 commissioner of the Health and Human Services Commission.

1-33 (2) "Institutional review board" means a  
1-34 compassionate-use institutional review board established under  
1-35 Section 487.253.

1-36 Sec. 487.252. RULES. (a) Except as otherwise provided by  
1-37 Subsection (b), the executive commissioner shall adopt all  
1-38 necessary rules to implement this subchapter, including rules  
1-39 designating the medical conditions for which a patient may be  
1-40 treated with low-THC cannabis as part of an approved research  
1-41 program conducted under this subchapter.

1-42 (b) The Texas Medical Board may adopt rules regarding the  
1-43 certification of a physician by an institutional review board.

1-44 Sec. 487.253. COMPASSIONATE-USE INSTITUTIONAL REVIEW  
1-45 BOARDS. (a) One or more compassionate-use institutional review  
1-46 boards may be established to:

1-47 (1) evaluate and approve proposed research programs to  
1-48 study the medical use of low-THC cannabis in treating a medical  
1-49 condition designated by rule of the executive commissioner under  
1-50 Section 487.252(a); and

1-51 (2) oversee patient treatment undertaken as part of an  
1-52 approved research program, including the certification of treating  
1-53 physicians.

1-54 (b) An institutional review board must be affiliated with a  
1-55 dispensing organization and meet one of the following conditions:

1-56 (1) be affiliated with a medical school, as defined by  
1-57 Section 61.501, Education Code;

1-58 (2) be affiliated with a hospital licensed under  
1-59 Chapter 241 that has at least 150 beds;

1-60 (3) be accredited by the Association for the

2-1 Accreditation of Human Research Protection Programs;  
2-2 (4) be registered by the United States Department of  
2-3 Health and Human Services, Office for Human Research Protections,  
2-4 in accordance with 21 C.F.R. Part 56; or

2-5 (5) be accredited by a national accreditation  
2-6 organization acceptable to the Texas Medical Board.

2-7 Sec. 487.254. REPORTS BY INSTITUTIONAL REVIEW BOARDS. Each  
2-8 institutional review board shall submit written reports that  
2-9 describe and assess the research findings of each approved research  
2-10 program to:

2-11 (1) the Health and Human Services Commission, not  
2-12 later than October 1 of each year; and

2-13 (2) the legislature, not later than October 1 of each  
2-14 even-numbered year.

2-15 Sec. 487.255. PATIENT TREATMENT. (a) Patient treatment  
2-16 provided as part of an approved research program under this  
2-17 subchapter may be administered only by a physician certified by an  
2-18 institutional review board to participate in the program.

2-19 (b) A patient participating in a research program under this  
2-20 subchapter must be a permanent resident of this state.

2-21 Sec. 487.256. INFORMED CONSENT. (a) Before receiving  
2-22 treatment under an approved research program, each patient must  
2-23 sign a written informed consent form.

2-24 (b) If the patient is a minor or lacks the mental capacity to  
2-25 provide informed consent, a parent, guardian, or conservator may  
2-26 provide informed consent on the patient's behalf.

2-27 (c) An institutional review board overseeing a research  
2-28 program under this subchapter may adopt a form to be used for the  
2-29 informed consent required by this section.

2-30 SECTION 2. Section 169.001(3), Occupations Code, is amended  
2-31 to read as follows:

2-32 (3) "Low-THC cannabis" means the plant Cannabis sativa  
2-33 L., and any part of that plant or any compound, manufacture, salt,  
2-34 derivative, mixture, preparation, resin, or oil of that plant that  
2-35 contains not more than one [0.5] percent by weight of  
2-36 tetrahydrocannabinols.

2-37 SECTION 3. Section 169.002, Occupations Code, is amended by  
2-38 adding Subsection (c) to read as follows:

2-39 (c) A physician is qualified to prescribe low-THC cannabis  
2-40 for the treatment of a patient with a medical condition approved by  
2-41 rule of the executive commissioner of the Health and Human Services  
2-42 Commission for treatment in an approved research program conducted  
2-43 under Subchapter F, Chapter 487, Health and Safety Code, if the  
2-44 physician is:

2-45 (1) licensed under this subtitle; and

2-46 (2) certified by a compassionate-use institutional  
2-47 review board created under Section 487.253, Health and Safety Code,  
2-48 that oversees patient treatment undertaken as part of that approved  
2-49 research program.

2-50 SECTION 4. Section 169.003, Occupations Code, is amended to  
2-51 read as follows:

2-52 Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A physician  
2-53 described by Section 169.002 may prescribe low-THC cannabis to a  
2-54 patient if:

2-55 (1) the patient is a permanent resident of the state;

2-56 (2) the physician complies with the registration  
2-57 requirements of Section 169.004; and

2-58 (3) the physician certifies to the department that:

2-59 (A) the patient is diagnosed with:

2-60 (i) epilepsy;

2-61 (ii) a seizure disorder;

2-62 (iii) multiple sclerosis;

2-63 (iv) spasticity;

2-64 (v) amyotrophic lateral sclerosis;

2-65 (vi) autism;

2-66 (vii) [~~terminal~~] cancer; [~~or~~]

2-67 (viii) an incurable neurodegenerative

2-68 disease;

2-69 (ix) post-traumatic stress disorder; or

3-1 (x) a medical condition that is approved  
3-2 for a research program under Subchapter F, Chapter 487, Health and  
3-3 Safety Code, and for which the patient is receiving treatment under  
3-4 that program; and

3-5 (B) the physician determines the risk of the  
3-6 medical use of low-THC cannabis by the patient is reasonable in  
3-7 light of the potential benefit for the patient.

3-8 SECTION 5. Section 169.001(6), Occupations Code, is  
3-9 repealed.

3-10 SECTION 6. (a) Not later than December 1, 2021, the  
3-11 executive commissioner of the Health and Human Services Commission  
3-12 shall adopt rules as necessary under Section 487.252, Health and  
3-13 Safety Code, as added by this Act.

3-14 (b) Not later than December 1, 2021, the public safety  
3-15 director of the Department of Public Safety shall adopt or amend  
3-16 department rules regarding the cultivation, processing, and  
3-17 dispensing of low-THC cannabis by a licensed dispensing  
3-18 organization under Chapter 487, Health and Safety Code.

3-19 SECTION 7. This Act takes effect September 1, 2021.

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