

SENATE AMENDMENTS

2nd Printing

By: Klick, Dean, Price, Oliverson, Howard,
et al.

H.B. No. 1535

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
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 five [~~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) 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) a condition that causes chronic pain,
- 6 for which a physician would otherwise prescribe an opioid;
- 7 (x) post-traumatic stress disorder;
- 8 (xi) a medical condition that is approved
- 9 for a research program under Subchapter F, Chapter 487, Health and
- 10 Safety Code, and for which the patient is receiving treatment under
- 11 that program; or
- 12 (xii) a debilitating medical condition
- 13 designated by the Department of State Health Services under
- 14 Subsection (b); and

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

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

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22 repealed.

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

27 (b) Not later than December 1, 2021, the public safety

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1 director of the Department of Public Safety shall adopt or amend
2 department rules regarding the cultivation, processing, and
3 dispensing of low-THC cannabis by a licensed dispensing
4 organization under Chapter 487, Health and Safety Code.

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

ADOPTED

By: Schwertner

Substitute the following for H.B. No. 1535:

By: [Signature]

MAY 25 2021

H.B. No. 1535
Lacey Davis
Secretary of the Senate

C.S. H .B. No. 1535

A BILL TO BE ENTITLED

AN ACT

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

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

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(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

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

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22 organization acceptable to the Texas Medical Board.

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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
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14 Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A physician
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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:

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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.

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 87TH LEGISLATIVE REGULAR SESSION

May 27, 2021

TO: Honorable Dade Phelan, Speaker of the House, House of Representatives

FROM: Jerry McGinty, Director, Legislative Budget Board

IN RE: HB1535 by Klick (Relating to the medical use of low-THC cannabis by patients with certain medical conditions and the establishment of compassionate-use institutional review boards to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in the treatment of certain patients.), **As Passed 2nd House**

No significant fiscal implication to the State is anticipated.

The bill would amend Health and Safety Code Chapter 487 to require the Health and Human Services Commission (HHSC) to establish one or more compassionate-use institutional review boards to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in treating certain conditions and oversee patient treatment undertaken as part of the approved research program. The bill would require patient treatment provided as part of an approved research program to be administered only by a physician certified by an institutional review board to participate in the program. The Texas Medical Board (TMB) would be required to adopt rules regarding the certification of a physician participating in the program.

Each institutional review board would be required to submit written reports to HHSC no later than October 1 of each year; and the legislature no later than October 1 of each even-number year.

The bill would require the executive commissioner of HHSC to adopt rules as necessary for the proposed research programs no later than December 1, 2021. Additionally, the Department of Public Safety (DPS) would be required to adopt or amend rules regarding the cultivation, processing and dispensing of low-THC cannabis by a licensed dispensing organization under Health and Safety Code Chapter 487 by December 1, 2021.

The bill would also amend Occupations Code Chapter 169 to add to the list of conditions for which a physician could prescribe low-THC cannabis to a patient.

DPS, TMB, and HHSC indicate any cost to implement provisions of the bill would be minimal and could be absorbed within available resources.

Local Government Impact

No significant fiscal implication to units of local government is anticipated.

Source Agencies: 405 Department of Public Safety, 503 Texas Medical Board, 529 Hlth & Human Svcs Comm, 537 State Health Services

LBB Staff: JMc, LBO, CMA, AKI, JLI

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 87TH LEGISLATIVE REGULAR SESSION

May 24, 2021

TO: Honorable Bryan Hughes, Chair, Senate Committee on State Affairs

FROM: Jerry McGinty, Director, Legislative Budget Board

IN RE: HB1535 by Klick (relating to the medical use of low-THC cannabis by patients with certain medical conditions and the establishment of compassionate-use institutional review boards to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in the treatment of certain patients.), **Committee Report 2nd House, Substituted**

No significant fiscal implication to the State is anticipated.

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The bill would require the executive commissioner of HHSC to adopt rules as necessary for the proposed research programs no later than December 1, 2021. Additionally, the Department of Public Safety (DPS) would be required to adopt or amend rules regarding the cultivation, processing and dispensing of low-THC cannabis by a licensed dispensing organization under Health and Safety Code Chapter 487 by December 1, 2021.

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LBB Staff: JMc, CMA, AKI, JLI

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 87TH LEGISLATIVE REGULAR SESSION

May 24, 2021

TO: Honorable Bryan Hughes, Chair, Senate Committee on State Affairs

FROM: Jerry McGinty, Director, Legislative Budget Board

IN RE: HB1535 by Klick (Relating to the medical use of low-THC cannabis by patients with certain medical conditions and the establishment of compassionate-use institutional review boards to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in the treatment of certain patients.), **As Engrossed**

No significant fiscal implication to the State is anticipated.

The bill would amend Health and Safety Code Chapter 487 to require the Health and Human Services Commission (HHSC) to establish one or more compassionate-use institutional review boards to evaluate proposed research programs to study the medical use of low-THC cannabis in treating certain conditions and oversee patient treatment undertaken as part of the approved research program. The bill would require patient treatment provided as part of an approved research program to be administered only by a physician certified by an institutional review board to participate in the program. The Texas Medical Board (TMB) would be required to adopt rules regarding the certification of a physician participating in the program.

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The bill would also amend Occupations Code Chapter 169 to add a definition and a list of conditions in which a physician could prescribe low-THC cannabis to a patient. The Department of State Health Services (DSHS) would be required to develop rules to designate debilitating medical conditions in which a physician may prescribe low-THC cannabis.

DPS, TMB, HHSC, and DSHS indicate any cost to implement provisions of the bill would be minimal and could be absorbed within available resources.

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LBB Staff: JMc, SMAT, AKI, JLI

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 87TH LEGISLATIVE REGULAR SESSION

April 6, 2021

TO: Honorable Stephanie Klick, Chair, House Committee on Public Health

FROM: Jerry McGinty, Director, Legislative Budget Board

IN RE: **HB1535** by Klick (Relating to the medical use of low-THC cannabis by patients with certain medical conditions and the establishment of compassionate-use institutional review boards to evaluate and approve proposed research programs to study the medical use of low-THC cannabis in the treatment of certain patients.), **As Introduced**

No significant fiscal implication to the State is anticipated.

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DPS, TMB, HHSC, and DSHS indicate any cost to implement provisions of the bill would be minimal and could be absorbed within available resources.

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