

BILL ANALYSIS

H.B. 1535
By: Klick
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

There have been calls to make certain updates to the Texas Compassionate-Use Act and to make more medical conditions eligible for treatment using low-THC cannabis. Furthermore, it has been suggested that more research is needed to help better understand the potential benefits of the medical use of low-THC cannabis. H.B. 1535 seeks to address these issues by establishing 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 and by expanding those medical conditions eligible for such treatment.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission and the Texas Medical Board in SECTION 1 of this bill, to the Department of State Health Services in SECTION 4 of this bill, and to the public safety director of the Department of Public Safety in SECTION 6 of this bill.

ANALYSIS

H.B. 1535 amends the Health and Safety Code to authorize the establishment of one or more compassionate-use institutional review boards to do the following:

- evaluate and approve proposed research programs to study the medical use of low-THC cannabis in treating a medical condition designated by applicable rule of the executive commissioner of the Health and Human Services Commission (HHSC); and
- oversee patient treatment undertaken as part of an approved research program, including the certification of treating physicians.

An institutional review board must be affiliated with a dispensing organization and meet one of the following conditions:

- be affiliated with a medical school;
- be affiliated with a hospital licensed under the Texas Hospital Licensing Law that has at least 150 beds;
- be accredited by the Association for the Accreditation of Human Research Protection Programs;
- be registered by the U.S. Department of Health and Human Services, Office for Human Research Protections, in accordance with federal regulations; or
- be accredited by a national accreditation organization acceptable to the Texas Medical Board (TMB).

H.B. 1535 requires each institutional review board to submit written reports that describe and assess the research findings of each approved research program to HHSC not later than October 1 of each year and to the legislature not later than October 1 of each even-numbered year.

H.B. 1535 limits patient treatment provided as part of an approved research program to treatment administered by a physician certified by an institutional review board to participate in the program and requires a patient participating in a research program to be a permanent Texas resident. The bill authorizes the TMB to adopt rules regarding the certification of a physician by an institutional review board.

H.B. 1535 requires each patient to sign a written informed consent form before receiving treatment under an approved research program. If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf. The bill authorizes an institutional review board overseeing a research program to adopt a form to be used for the informed consent.

H.B. 1535 requires the executive commissioner of HHSC, not later than December 1, 2021, to adopt all necessary rules to implement provisions relating to compassionate-use research and reporting, 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 those provisions.

H.B. 1535 amends the Occupations Code to increase from one-half of one percent to five percent the maximum percent by weight of THC allowable in cannabis for that cannabis to be considered low-THC for purposes of prescribing low-THC cannabis to certain patients for compassionate use. The bill defines "veteran" for those purposes.

H.B. 1535 establishes that a physician is qualified to prescribe low-THC cannabis for the treatment of a patient with a medical condition approved by executive commissioner rule for treatment in an approved research program conducted under the bill's provisions relating to compassionate-use research and reporting if the physician meets the following criteria:

- is certified by a compassionate-use institutional review board created under those provisions that oversees patient treatment undertaken as part of that approved research program; and
- is licensed under the Medical Practice Act.

H.B. 1535 expands the medical conditions for which a patient may be prescribed low-THC cannabis for compassionate use to include the following:

- a condition that causes acute or chronic pain, for which a physician would otherwise prescribe an opioid;
- post-traumatic stress disorder, for a patient who is a veteran;
- a medical condition that is approved for a research program and for which the patient is receiving treatment under that program; or
- a debilitating medical condition designated by the Department of State Health Services (DSHS).

The bill clarifies that a diagnosis of cancer does not have to be a terminal diagnosis for purposes of qualifying for such a prescription. The bill authorizes DSHS by rule to designate debilitating medical conditions for which a physician may prescribe low-THC cannabis for compassionate use.

H.B. 1535 requires the public safety director of the Department of Public Safety (DPS), not later than December 1, 2021, to adopt or amend DPS rules regarding the cultivation, processing, and dispensing of low-THC cannabis by a licensed dispensing organization under the Texas Compassionate-Use Act.

H.B. 1535 repeals Section 169.001(6), Occupations Code.

EFFECTIVE DATE

September 1, 2021.