

## **BILL ANALYSIS**

C.S.H.B. 46  
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Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

In 2015, the Texas Legislature enacted S.B. 339, which provided for the first legal use of low-THC cannabis for compassionate use in Texas. The bill author has informed the committee that this authorization was initially limited to patients with intractable epilepsy, but it was expanded in 2019 and 2021 to include other conditions. However, there are other patients who could benefit from inclusion in this authorization and some obstacles to providing needed services to Texans persist. C.S.H.B. 46 seeks to resolve these issues by expanding the Texas Compassionate-Use Program, with the proper safeguards. The bill, among other provisions, allows license holders to open secure storage facilities without the need for additional licenses, requires the Department of Public Safety to issue 11 licenses to dispensing organizations in an attempt to house one in each public health region, limits prescription quantities, provides for the authorized use of prescribed inhalers, and expands the medical conditions for which low-THC cannabis may be prescribed.

### **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 public safety director of the Department of Public Safety in SECTIONS 6, 7, and 8 of this bill and to the executive commissioner of the Health and Human Services Commission in SECTIONS 15 and 16 of this bill.

### **ANALYSIS**

C.S.H.B. 46 amends the Health and Safety Code, with respect to a dispensing organization licensed under applicable state law to cultivate, process, and dispense low-THC cannabis to a patient for whom low-THC cannabis is prescribed for compassionate use, to authorize such an organization to operate one or more satellite locations in addition to the organization's primary location to securely store low-THC cannabis for distribution. The bill provides the following:

- a satellite location must be approved by the Department of Public Safety (DPS) before a licensed dispensing organization may operate the location;
- a licensed dispensing organization may apply for approval in the form and manner prescribed by DPS;
- DPS must act on such a submitted application not later than the 180th day after the date the application is submitted to DPS;
- the public safety director of DPS must adopt rules regarding the design and security requirements for satellite locations; and

- a dispensing organization may not operate more than one satellite location in a public health region designated under the Local Public Health Reorganization Act until the dispensing organization operates one satellite location in each public health region.

The bill requires an application for a license to operate as a dispensing organization to include the address of any satellite location that will be used by the applicant for secure storage of low-THC cannabis as provided by the bill. The bill establishes that a licensed dispensing organization is not required to apply for an additional license for the use of a satellite location for secure storage of low-THC cannabis if the address of the satellite location was included in the application or the organization obtains approval from DPS as provided by the bill.

C.S.H.B. 46 requires an individual who is an owner or member of a dispensing organization to apply for and obtain a registration relating to the operation of a dispensing organization. Accordingly, the bill does the following:

- requires DPS to register owners and members of each dispensing organization;
- includes among the eligibility requirements for an initial or renewal license to operate as a dispensing organization that the license applicant's owners and members are registered;
- includes among the information that must be included in an application for an initial or renewal license to operate as a dispensing organization the name and address of each of the applicant's owners and members; and
- includes the applicant's owners and members among the individuals whose names the applicant must provide to DPS and who must pass a criminal history background check before a licensee may transfer the license to another person.

C.S.H.B. 46 establishes that, if DPS denies the issuance of a license to operate as a dispensing organization to an applicant that has never held such a license, the applicant is not entitled to a hearing. The bill requires DPS to issue 11 licenses to dispensing organizations in Texas provided that DPS receives applications from a sufficient number of applicants meeting the requirements for eligibility to operate as a dispensing organization under applicable state law. The bill requires DPS to issue and renew licenses in a manner that ensures adequate access to low-THC cannabis for patients registered in the compassionate-use registry in each public health region designated under the Local Public Health Reorganization Act. The bill requires the director to adopt rules to establish a timeline for reviewing and taking action on an application for a license to operate as a dispensing organization.

C.S.H.B. 46 establishes that information within the compassionate use registry regarding patient identification, including the fact that a person is listed as a patient in the registry, is confidential and may only be accessed by DPS, registered physicians, and dispensing organizations for the purposes of provisions relating to the compassionate use of low-THC cannabis in Texas. The bill prohibits such confidential information from being disclosed except as otherwise authorized under those provisions and establishes that the information is not subject to disclosure under state public information law. The bill authorizes DPS, on request by a patient, to release patient information contained in the registry to the patient or a person designated by the patient.

C.S.H.B. 46 requires an applicant issued a license to operate a dispensing organization to begin dispensing low-THC cannabis not later than 24 months after the date the license is issued and continue dispensing low-THC cannabis during the term of the issued license. The bill requires the director to adopt rules to do the following:

- monitor whether a licensed dispensing organization is using the license to dispense low-THC cannabis; and
- revoke the license of a dispensing organization that does not dispense low-THC cannabis within the time required by the bill or that discontinues dispensing low-THC cannabis during the term of a license.

C.S.H.B. 46 prohibits a dispensing organization from dispensing to a person low-THC cannabis in a package or container that contains more than a total of 1.2 grams of tetrahydrocannabinols. The bill also prohibits a dispensing organization from dispensing a low-THC cannabis product

that contains a cannabinoid that is not a phytocannabinoid and from including in a product any naturally occurring chemical substance from the cannabis plant that is not a phytocannabinoid, unless the dispensing organization obtains approval from DPS. For these purposes, the bill defines "phytocannabinoid" as a chemical substance:

- created naturally by a plant of the species *Cannabis sativa* L. that is separated from the plant by a mechanical or chemical extraction process;
- created naturally by a plant of the species *Cannabis sativa* L. that binds to or interacts with the cannabinoid receptors of the endocannabinoid system; or
- produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst.

C.S.H.B. 46 prohibits a municipality, county, or other political subdivision from enacting, adopting, or enforcing a rule, ordinance, resolution, or other regulation that prohibits the authorized storage of low-THC cannabis under state law.

C.S.H.B. 46 amends the Occupations Code to include among the medical conditions for which a patient's diagnosis authorizes a physician to prescribe low-THC cannabis for compassionate use to the patient who is otherwise eligible for that prescription:

- a condition that causes chronic pain, for which a physician would otherwise prescribe an opioid;
- glaucoma;
- traumatic brain injury;
- spinal neuropathy;
- Crohn's disease or other inflammatory bowel disease;
- degenerative disc disease;
- a terminal illness or a condition for which a patient is receiving hospice or palliative care; and
- a medical condition designated by the Department of State Health Services (DSHS) under the bill.

The bill also includes an otherwise eligible patient who is an honorably discharged veteran who would benefit from medical use to address a medical condition among the patients who may be prescribed low-THC cannabis for compassionate use.

C.S.H.B. 46 establishes that each prescription issued by a physician to a patient for low-THC cannabis may only provide for a 90-day supply of low-THC cannabis based on the dosage prescribed to the patient and may provide up to four refills of a 90-day supply of low-THC cannabis. The bill authorizes DSHS to designate medical conditions for which a physician may prescribe low-THC cannabis and requires the executive commissioner of the Health and Human Services Commission (HHSC) to adopt rules for the approval of those medical conditions. The bill authorizes a physician, if a patient is diagnosed with a medical condition not specified in statute as diagnoses for which a patient may be prescribed low-THC cannabis, to submit to DSHS a request for DSHS to designate the condition as a medical condition for which a physician may prescribe low-THC cannabis. The request must be accompanied by medical evidence such as peer-reviewed published research demonstrating that low-THC cannabis may be beneficial to treat that medical condition. The bill requires the executive commissioner by rule to prescribe the manner in which a physician may submit such a request.

C.S.H.B. 46 provides for the following:

- a physician may prescribe pulmonary inhalation of an aerosol or vapor as a means of administration of low-THC cannabis if the physician determines that based on the patient's condition there is a medical necessity for that means of administration; and
- the executive commissioner must adopt rules related to medical devices for pulmonary inhalation of low-THC cannabis and establishing an amount of tetrahydrocannabinols when administered by pulmonary inhalation that is medically equivalent to other means of administering low-THC cannabis.

C.S.H.B. 46, with respect to definitions that are applicable to provisions relating to a physician's authority to prescribe low-THC cannabis to certain patients for compassionate use, does the following:

- revises the definition of "low-THC cannabis" by:
  - specifying that the one percent maximum of tetrahydrocannabinols by weight that may be contained in cannabis for it to be considered low-THC cannabis is one percent by weight of tetrahydrocannabinols in each dosage unit; and
  - establishing that, for tetrahydrocannabinol administered by pulmonary inhalation as prescribed by executive commissioner rule, the maximum allowable amount of tetrahydrocannabinol is an amount equivalent to the allowable amount otherwise authorized by law and as amended by the bill;
- includes absorption, inhalation, or insertion by a means of administration other than by smoking of a prescribed amount of low-THC cannabis by a person for whom low-THC cannabis is prescribed among the consumption methods considered "medical use";
- excludes from the definition of "smoking" inhaling a medication or other substance that is otherwise aerosolized or vaporized for administration by pulmonary inhalation; and
- defines "veteran" as a person who has served in:
  - the army, navy, air force, coast guard, or marine corps of the United States;
  - the state military forces, defined by reference as the Texas National Guard, the Texas State Guard, and any other active militia or military force organized under state law; or
  - an auxiliary service of one of those branches of the armed forces.

C.S.H.B. 46 requires the director of DPS to adopt the rules necessary to implement the bill's provisions relating to the compassionate use of low-dose THC cannabis in Texas not later than October 1, 2025, and requires the executive commissioner of HHSC to adopt rules necessary to implement the bill's provisions relating to the prescription of low-THC cannabis and the administration of low-THC cannabis by pulmonary inhalation not later than that date.

### **EFFECTIVE DATE**

September 1, 2025.

### **COMPARISON OF INTRODUCED AND SUBSTITUTE**

While C.S.H.B. 46 may differ from the introduced in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

Both the introduced and the substitute authorize a licensed dispensing organization to operate one or more satellite locations in addition to the organization's primary location to securely store low-THC cannabis for distribution, but differ in the following ways:

- the substitute includes a provision absent from the introduced requiring DPS to act on a submitted application to operate a satellite location not later than the 180th day after the date the application is submitted to DPS;
- the substitute includes a provision absent from the introduced prohibiting a dispensing organization from operating more than one satellite location in a public health region designated under the Local Public Health Reorganization Act until the dispensing organization operates one satellite location in each public health region; and
- the substitute requires the director to adopt rules regarding the design and security requirements for satellite locations, whereas the introduced required DPS to do so.

The substitute includes provisions absent from the introduced that do the following:

- requires an individual who is an owner or member of a dispensing organization to apply for and obtain a registration relating to the operation of a dispensing organization;

- requires DPS to register owners and members of each dispensing organization;
- includes among the eligibility requirements for an initial or renewal license to operate as a dispensing organization that the license applicant's owners and members are registered;
- includes among the information that must be included in an application for an initial or renewal license to operate as a dispensing organization the name and address of each of the applicant's owners and members;
- includes the applicant's owners and members among the individuals whose names the applicant must provide to DPS and who must pass a criminal history background check before a licensee may transfer the license to another person;
- establishes that an applicant for a license to operate as a dispensing organization is not entitled to a hearing if DPS denies the issuance of the license and the applicant has never held such a license; and
- requires the director to adopt rules to establish a timeline for reviewing and taking action on an application for such a license.

Whereas the introduced required DPS to issue 11 licenses to dispensing organizations in Texas provided that DPS receives applications from a sufficient number of applicants meeting the requirements for approval to operate as a dispensing organization, the substitute requires DPS to do so provided that DPS receives applications from a sufficient number of applicants meeting the requirements for eligibility to operate as a dispensing organization.

The substitute includes provisions absent from the introduced that do the following:

- establishes that certain information within the compassionate use registry is confidential and may only be accessed by DPS, registered physicians, and dispensing organizations for certain purposes;
- prohibits such confidential information from being disclosed except as otherwise authorized by applicable law and establishes that the information is not subject to disclosure under state public information law;
- authorizes DPS to release patient information contained in the registry to the patient or a person designated by the patient on the patient's request;
- prohibits a dispensing organization from dispensing a low-THC cannabis product that contains a cannabinoid that is not a phytocannabinoid and from including in a product any naturally occurring chemical substance from the cannabis plant that is not a phytocannabinoid, unless the dispensing organization obtains approval from DPS;
- defines "phytocannabinoid" for that purpose;
- expands the medical conditions for which a patient's diagnosis authorizes a physician to prescribe low-THC cannabis for compassionate use to a patient who is otherwise eligible for that prescription;
- includes an otherwise eligible patient who is an honorably discharged veteran who would benefit from medical use to address a medical condition in the patients who may be prescribed low-THC cannabis for compassionate use;
- establishes that each prescription issued by a physician to a patient for low-THC cannabis may provide up to four refills of a 90-day supply of low-THC cannabis;
- authorizes DSHS to designate medical conditions for which a physician may prescribe low-THC cannabis and requires the executive commissioner to adopt rules for the approval of those medical conditions;
- provides for the procedure by which a physician may request the designation of a condition as a medical condition for that purpose;  
requires the executive commissioner to adopt rules necessary to implement provisions relating to the prescription of low-THC cannabis by a certain date; and
- requires the executive commissioner to adopt rules establishing an amount of tetrahydrocannabinols when administered by pulmonary inhalation that is medically equivalent to other means of administering low-THC cannabis.

Both the introduced and the substitute make changes to certain definitions that are applicable to provisions relating to a physician's authority to prescribe low-THC cannabis to certain patients for compassionate use. However, the bill versions differ as follows:

- with respect to the definition of "medical use," the introduced included absorption or insertion by a means of administration other than by smoking of a prescribed amount of low-THC cannabis by a person for whom low-THC cannabis is prescribed, whereas the substitute includes absorption, inhalation or insertion by a means of administration other than by smoking of a prescribed amount of low-THC cannabis by a person for whom low-THC cannabis is prescribed;
- with respect to the definition of "low-THC cannabis," the introduced changed the maximum allowable amount of tetrahydrocannabinols that may be contained in cannabis for it to be considered low-THC cannabis for medical use from one percent by weight of tetrahydrocannabinols to 20 milligrams of tetrahydrocannabinols in each dosage unit, whereas the substitute instead changes such maximum allowable amount to one percent by weight of tetrahydrocannabinols in each dosage unit and establishes that, for tetrahydrocannabinol administered by pulmonary inhalation as prescribed by executive commissioner rule, the maximum allowable amount of tetrahydrocannabinol is an amount equivalent to the allowable amount otherwise authorized by law and as amended by the bill; and
- the substitute includes definitions for "veteran" and "executive commissioner," which did not appear in the introduced.

Whereas the introduced required DPS to adopt rules necessary to implement provisions relating to satellite locations and relating to requirements for license holders to begin and maintain operations by a certain date, the substitute requires the director of DPS to adopt the rules necessary to implement any of the bill's provisions relating to the compassionate use of low-dose THC cannabis in Texas not later than a certain date.