BILL ANALYSIS

C.S.H.B. 1365
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

It has been suggested that the medical use of low-THC cannabis may be a beneficial treatment for an array of debilitating medical conditions. However, there are concerns regarding the lack of a statutory framework and appropriate authorizations regulating the proper use of low-THC cannabis for such purposes. C.S.H.B. 1365 seeks to establish such a regulatory scheme and authorizations by providing for the possession, use, cultivation, processing, distribution, transportation, and delivery of low-THC cannabis for medical use by patients with certain debilitating medical conditions and for the licensing of dispensing organizations, research organizations, and testing facilities.

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, 8, 12, and 27 of this bill.

ANALYSIS

C.S.H.B. 1365 amends the Health and Safety Code and Occupations Code to set out provisions relating to the authorized use of low-THC cannabis and the licensing of certain related entities. The bill authorizes a physician to prescribe low-THC cannabis for a patient with a debilitating medical condition, as defined by the bill, provided that the physician has obtained the proper medical knowledge concerning medical use as treatment for the patient's particular debilitating medical condition through a course of instruction provided for that purpose, continuing medical education relating to medical use, or self-study.

C.S.H.B. 1365 revises provisions relating to the authorized prescribing of low-THC cannabis as follows:

- requires a physician to add a prescription for low-THC cannabis for a patient to the physician's registration information before the physician may make such prescription;
- authorizes the Department of Public Safety (DPS) to publish the name of a registered physician only if permission is expressly granted by the physician, and provides that the physician's name is confidential and not subject to disclosure under state public information law;
- requires the physician to certify to DPS that:
    - there is a bona fide physician-patient relationship as defined by the bill;
    - the patient is diagnosed with a debilitating medical condition;

    - the physician has determined the risk of low-THC cannabis use by the patient is reasonable in light of the potential benefit for the patient; and
    - the physician has obtained the proper medical knowledge;
- requires the physician to record any adverse event in the patient's medical records and to report any serious adverse event to the cannabis therapeutic research review board; and
- prohibits a physician from being denied any right or privilege or being subjected to any disciplinary action solely for making a written or oral statement that, in the physician's professional opinion, the potential benefits of the use of cannabis would likely outweigh the health risks or for participating in cannabis therapeutic research programs.

The bill provides for the definitions of "prescribe," "prescription," and "serious adverse effect."

C.S.H.B. 1365 replaces the controlled substance therapeutic research program review board with a cannabis therapeutic research review board for purposes of administering the cannabis therapeutic research program. The bill requires the executive commissioner of the Health and Human Services Commission to assist the review board. The bill provides for the composition and administration of the 12-member review board, which is appointed by the governor, and authorizes the review board to create and appoint certain advisory committees. The bill authorizes research programs to be conducted with a medical school, a licensed hospital, or a general academic teaching institution and to investigate the safety and efficacy of low-THC cannabis and other public health outcomes. The bill sets out provisions relating to the research programs. The bill transfers the duties of the controlled substance therapeutic research program review board to the cannabis therapeutic research review board as of the bill's effective date and requires the governor to appoint the additional members not later than October 1, 2019.

C.S.H.B. 1365 requires DPS to develop a form for a patient listed in the compassionate-use registry to designate one caregiver, as defined by the bill, and one alternate caregiver and sets out limitations for such designations. The bill requires the public safety director of DPS to adopt rules necessary to implement the bill's provisions relating to the designation of caregivers, including rules allowing a patient to change the patient's caregiver or alternate caregiver and to provide identification cards for registered caregivers.

C.S.H.B. 1365 excepts a cannabis research organization that researches the cultivation, analysis, and medical use of low-THC cannabis and a cannabis testing facility that analyzes the content, safety, and potency of low-THC cannabis, as authorized by an issued license, from the applicability of statutory provisions relating to pharmacy and pharmacists.

C.S.H.B. 1365 revises provisions of the Texas Controlled Substances Act and provisions of the Texas Compassionate-Use Act to set the allowable amount of low-THC cannabis for a person for whom medical use is prescribed, to set out labeling requirements for oils and products infused with low-THC cannabis, and to establish protection from legal action for a qualifying patient; a dispensing organization; a cannabis research organization; a cannabis testing facility; or a DPS-registered director, manager, or employee of a dispensing organization, cannabis research organization, or cannabis testing facility. The bill sets out provisions relating to the following:

- overcoming the presumption that a protected person has engaged in conduct constituting child abuse, neglect, or endangerment on the basis of authorized low-THC cannabis use;
- the denial, limitation, or restriction of parental rights on the basis of authorized low-THC cannabis use;
- the seizure or forfeiture of certain property used in relation to authorized low-THC cannabis; and
- the arrest, prosecution, or imposition of any sentence or penalty relating to possession, delivery, or manufacture of drug paraphernalia related to authorized low-THC cannabis use.

C.S.H.B. 1365 authorizes a dispensing organization to operate three additional retail dispensing locations under a single license issued by DPS on application to DPS. The bill authorizes a licensee to operate more than four dispensing locations if DPS determines that additional locations are necessary to meet patient access needs. The bill authorizes DPS to set a fee for an application for each additional location. The bill requires DPS, not later than September 1, 2020, to license at least 12 dispensing organizations, including those already licensed as of the bill's effective date, provided at least 12 applicants for a license to operate as a dispensing organization have met the requirements for approval.

C.S.H.B. 1365 requires a dispensing organization to provide to DPS a sample suitable for testing of low-THC cannabis dispensed by the organization on DPS request.

C.S.H.B. 1365 provides for cannabis testing facility and cannabis research organization licenses, sets out procedures for applying for an initial or renewal license, and establishes eligibility requirements for the licenses and duties for maintaining eligibility. The bill requires an individual who is a director, manager, or employee of a dispensing organization, cannabis testing facility, or cannabis research organization to apply for and obtain a registration under the Texas Compassionate-Use Act.

C.S.H.B. 1365 requires the public safety director of DPS to take the following actions:

- adopt by rule labeling requirements for low-THC cannabis that must ensure each oil and product infused with low-THC cannabis is labeled with the quantity of each cannabinoid and terpene contained in the oil or product;
- in consultation with the cannabis therapeutic research review board, adopt necessary rules to allow DPS to monitor the safety and efficacy of low-THC cannabis and oils or products infused with low-THC cannabis, including rules:
    - requiring accurate reporting to consumers by testing facilities regarding the content of low-THC cannabis and oils or products infused with low-THC cannabis; and
    - providing for random testing by DPS to ensure compliance with labeling and reporting requirements; and
- adopt reasonable fees in amounts sufficient to cover the cost of administering the cannabis therapeutic research program.

The bill authorizes DPS to use fees imposed under the Texas Compassionate-Use Act to establish a cannabis testing and quality control fund for the costs of equipment to test cannabis, cannabis products, and other substances for the purpose of assisting law enforcement to enforce provisions relating to substance abuse regulation and crimes.

C.S.H.B. 1365 authorizes the director, in consultation with the cannabis therapeutic research review board, to collect data from dispensing organizations, cannabis research organizations, cannabis testing facilities, and health care providers as necessary to enable DPS to monitor the safety and efficacy of low-THC cannabis and oils or products infused with low-THC cannabis and authorizes the director to adopt rules for such data collection.

C.S.H.B. 1365 requires the director, not later than December 1, 2019, to adopt rules as required to implement, administer, and enforce the Texas Compassionate-Use Act as amended by the bill. The bill requires DPS, not later than March 1, 2020, to begin licensing cannabis research organizations and cannabis testing facilities provided that the applicants for a license have met all requirements for approval. The bill establishes that a license to operate as a dispensing organization before the bill's effective date continues to be valid after the bill's effective date until that license expires and that the registration of a director, manager, or employee of a dispensing organization continues to be valid after the bill's effective date until that registration expires.

C.S.H.B. 1365 amends the Education Code to prohibit a student for whom low-THC cannabis was prescribed from being subject to suspension, expulsion, placement in a disciplinary alternative education program, or any other form of discipline solely because the student possessed, used, or was under the influence of the low-THC cannabis.

EFFECTIVE DATE

On passage, or, if the bill does not receive the necessary vote, September 1, 2019.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 1365 may differ from the original in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

The substitute changes the cannabis to which the bill's provisions apply from medical cannabis to low-THC cannabis and changes from recommending to prescribing the authorized method of providing access to such cannabis.

The substitute includes a provision prohibiting the suspension, expulsion, placement in a disciplinary alternative education program, or any other form of discipline solely because a student possessed, used, or was under the influence of prescribed low-THC cannabis.

The substitute includes provisions replacing the controlled substance therapeutic research program review board with a differently composed cannabis therapeutic research review board, transferring the duties of the controlled substance therapeutic review board to the cannabis therapeutic research review board, and requiring the governor to appoint certain members to the cannabis therapeutic research review board by a certain date. The substitute includes additional provisions relating to the cannabis therapeutic review board, including specifying that the public safety director of DPS consults with the cannabis therapeutic research review board in adopting certain rules and collecting certain data.

The substitute:

- includes licensing and other provisions relating to a cannabis research organization;
- includes such an organization in applicable provisions of the Texas Controlled Substances Act and the Texas Compassionate-Use Act; and
- includes a requirement for DPS to begin licensing cannabis research organizations by a certain date.

The substitute revises licensing eligibility requirements for a cannabis testing facility license.

The substitute includes an authorization for DPS to use certain fees to establish a cannabis testing and quality control fund.

The substitute includes provisions relating to the designation of caregivers for patients listed in the compassionate-use registry.

The substitute:

- includes authorization for a dispensing organization to operate additional retail dispensing locations under a single license subject to certain conditions;
- includes a requirement for a dispensing organization to provide a low-THC cannabis sample suitable for testing on DPS request;

- includes a requirement for DPS to license a certain number of dispensing organizations by a certain date; and
- does not include revisions to a dispensing organization's duties relating to dispensing medical cannabis.

The substitute changes the medical conditions considered to be debilitating medical conditions but does not include provisions relating to a petition for approval of a medical condition or symptom as a debilitating medical condition.

The substitute changes provisions specifying the allowable amount of low-THC cannabis for a patient.

The substitute includes:

- a provision requiring a physician who prescribes low-THC cannabis to certify that there is a bona fide physician-patient relationship;
- definitions for "bona fide physician-patient relationship," "prescribe," "prescription," and "serious adverse effect";
- a requirement for a physician to add a prescription for low-THC cannabis to the physician's registration information; and
- provisions relating to the confidentiality of a registered physician's name.

The substitute does not include a requirement for a physician to specify in the registration the amount of low-THC cannabis the physician recommends for a patient if the recommendation is above a certain amount.

The substitute includes provisions relating to adverse event reporting and prohibiting a physician from being denied any right or privilege or being subject to any disciplinary action solely for making a certain statement regarding the use of cannabis or participation in a cannabis therapeutic research program.