SUBJECT: Medical use of low-THC cannabis for patients with epilepsy

COMMITTEE: Public Health — favorable, without amendment

VOTE: 7 ayes — Naishtat, Blanco, Guerra, R. Miller, Sheffield, Zedler, Zerwas

1 nay — Crownover

3 absent — Coleman, Collier, S. Davis

SENATE VOTE: On final passage, May 7 — 26 – 5 (Birdwell, Creighton, Fraser, Hancock, V. Taylor)

WITNESSES: (*On House companion bill, CSHB 892*)
For —Leslie Moccia, CAFE Texas; Paige Figi, Coalition for Access Now and Realm of Caring; Dennis Borel, Coalition of Texans with Disabilities; and seven individuals; (*Registered, but did not testify*: Heiwa Salovitz, Adapt of Texas; Chuck Sparks, Victoria Ammann, Mary Lou Garcia, Lauren Wallace, Stephanie Fokas, Kevin Clark, Katie Graham, and Joanne Yurich, CAFE TX; Nancy Williams, City of Austin; Tanya Lavelle, Easter Seals Central Texas; Sindi Rosales and Shannon Robbins, Epilepsy Foundation Texas; Phillip Martin, Progress Texas; Gwendolyn Gholson and Joseph Ptak, Texans Smart on Crime; Patrick Moran, Texas Cannabis Industry Association; Andrew Cates, Texas Nurses Association; Jesse Romero, William C. Velasquez Institute; and 37 individuals)

Against — Richard Garcia, North Texas Crime Commission; Buddy Mills, William Travis, and AJ Louderback, Sheriffs' Association of Texas; Arthur Mayer; Christina Talley; Angus Wilfong; (*Registered, but did not testify*: Scott Peters, Dallas County Schools; Jeff Pender, DFW NORML; Paul Huang, Belinda Ramsey, and Christina Yampanis, North Texas Crime Commission; Curtis Howard, Plano Police Dept.; Murray Agnew, R Glenn Smith, Dennis D. Wilson, and Micah Harmon, Sheriffs Association of Texas; and 14 individuals)

On — Chris Ellis, Beacon Information Designs, LLC; Kathleen Gray,

Patient Aliance For Cannabis Therapeutics; Stephanie Williams, Texas Coalition of Compassionate Care; Sara Austin, Texas Medical Association; Dean Bortell; Timothy Dashner; Frank Dorval; (*Registered, but did not testify*: Caroline Turner, Denton NORML; Leah Jones, DFW NORML; Vincent Lopez, Patient Alliance for Cannabis Therapeutics; Belinda Williams, Texas Coalition for Compassionate Care; Mari Robinson, Texas Medical Board; and 22 individuals)

BACKGROUND:

Health and Safety Code, ch. 481.121 makes it a crime to knowingly or intentionally possess a usable quantity of marijuana. Offenses are punished according to the amount of marijuana possessed and range from a class B misdemeanor (up to 180 days in jail and/or a maximum fine of $2,000) for possession of up to two ounces to a felony punished with life in prison or a sentence of five to 99 years and an optional fine of up to $10,000 if the amount possessed was more than 2,000 pounds.

Health and Safety Code, ch. 481.002(26), defines marijuana to mean the plant Cannabis sativa L., whether growing or not, the seeds of that plant, and every compound, manufacture, salt, derivative, mixture, or preparation of that plant or its seeds.

Cannabidiol (CBD) is a type of chemical compound that is found in cannabis, according to the drug manufacturer GWPharma.

The U.S. Food and Drug Administration has not approved a marketing application for a drug product containing or derived from botanical marijuana.

DIGEST:

SB 339 would create the Texas Compassionate Use Act, under which the Department of Public Safety (DPS) would be required to license dispensers of low-THC cannabis to certain patients with intractable epilepsy and to establish and maintain a secure, online compassionate-use registry that would contain:

- the name of each physician who registered as a prescriber of low-THC cannabis for a patient;

- the name and date of birth of the patient;
- the dosage prescribed;
- the means of administration ordered, which could not include smoking;
- the total amount of low-THC cannabis required to fill the patient's prescription; and
- a record of each amount of low-THC cannabis dispensed by a dispensing organization to a patient under a prescription.

Under the bill, "low-THC cannabis" would mean the plant Cannabis sativa L. and any part of that plant or any compound, manufacture, salt, derivative, mixture, preparation, resin or oil of that plant that contained up to 0.5 percent by weight of tetrahydrocannabinols (THC) and at least 10 percent by weight of cannabidiol.

Registry. DPS would ensure that the registry was designed to prevent more than one qualified physician from registering as the prescriber for a single patient and that the registry was accessible to law enforcement agencies and dispensing organizations. The department also would ensure that the registry allowed a physician who was qualified to prescribe low-THC cannabis to input safety and efficacy data regarding treatment of patients using the prescription.

Prescribing physicians. A physician would be qualified to prescribe low-THC cannabis to a patient with intractable epilepsy if the physician dedicated a significant portion of clinical practice to the evaluation and treatment of epilepsy and held certain board certifications in epilepsy, neurology, neurology with special qualification in child neurology, or neurophysiology. A physician could prescribe low-THC cannabis to alleviate a patient's seizures if:

- the patient was a permanent resident of Texas;
- the physician complied with registration requirements under SB 339;
- the physician certified to DPS that the patient was diagnosed with intractable epilepsy;

- the physician determined the risk of the medical use of low-THC cannabis by the patient to be reasonable in light of the potential benefit for the patient;
- a second physician qualified to prescribe low-THC cannabis had concurred with the first physician's determination and the second physician's concurrence was recorded in the patient's medical record;
- the physician was registered as the prescriber for the patient in the compassionate-use registry maintained by DPS; and
- the physician maintained a patient treatment plan containing certain information specified in the bill.

Dispensing organizations. SB 339 would require an organization that cultivated, processed, or dispensed low-THC cannabis (dispensing organization) to have a license and would set eligibility requirements for obtaining it. A license would be valid for two years from the date of issue or renewal. DPS would issue or renew a license to operate a dispensing organization if the organization met certain eligibility requirements and if issuing the license was necessary to ensure reasonable statewide access to and availability of low-THC cannabis for patients registered in the compassionate-use registry and for whom low-THC cannabis was prescribed.

A person applying for a new or renewed license would be required to provide DPS with their name and the name of each of the organization's directors, managers, and employees, upon whom the department would conduct fingerprinting and a background check. If a licensed dispensing organization hired a new manager or employee, the organization would have to provide DPS with the name of the prospective manager or employee. The organization could not transfer its license to another person before the prospective applicant and the applicant's directors, managers, and employees provided fingerprints and passed a background check.

If DPS denied the issuance or renewal of a license, the organization that applied would be entitled to a hearing. The department would give written notice of the grounds of denial within 30 days before the date of the

hearing. The department could suspend or revoke an issued license at any time if it determined that the licensee had not met the eligibility requirements for the license or had failed to comply with the provisions of the bill.

After suspending or revoking a license, the director of DPS could seize or place under seal all low-THC cannabis and drug paraphernalia owned or possessed by the dispensing organization. The seized items could not be disposed of until the time for an organization to administratively appeal the order had elapsed or until all appeals had ended. When a revocation order became final, all low-THC cannabis and drug paraphernalia could be forfeited to the state.

SB 339 would require an organization that dispensed low-THC cannabis to record in the compassionate-use registry the form and quantity of the low-THC cannabis dispensed and when it was dispensed. An organization also would be required to verify the validity of a person's prescription before dispensing the drug. The organization would verify that the prescription:

- was for a person listed as a patient in the compassionate-use registry;
- matched the entry in the compassionate-use registry relating to the total amount of cannabis required to fill the prescription; and
- had not previously been filled by a dispensing organization as indicated by an entry in the compassionate-use registry.

Exceptions to current laws. The bill would prohibit a municipality, county, or other political subdivision from enacting, adopting, or enforcing any type of regulation that would prohibit the cultivation, production, dispensing, or possession of low-THC cannabis, as authorized by SB 339.

SB 339 would exempt a person who engaged in the acquisition, possession, production, cultivation, delivery, or disposal of a raw material used in or by-product created by the production or cultivation of low-THC

cannabis from certain marijuana offenses if the person:

- was a patient or the legal guardian of a patient for whom low-THC cannabis was prescribed and the person had a valid prescription from a dispensing organization; or
- was a director, manager, or employee of a dispensing organization and the person solely acquired, possessed, produced, cultivated, dispensed, or disposed of low-THC cannabis, raw materials, or related drug paraphernalia as part of the person's regular duties at the organization.

The bill also would allow a dispensing organization licensed under the provisions of SB 339 to possess low-THC cannabis as a controlled substance without registering with the director of DPS. The Texas Pharmacy Act also would not apply to dispensing organizations.

Rules and effective date. The public safety director would adopt rules by December 1, 2015, to implement, administer, and enforce the provisions of SB 339, including rules to establish the compassionate-use registry. By September 1, 2017, DPS would license at least three dispensing organizations in accordance with the bill, provided at least three applicants met the requirements for approval.

This bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2015.

SUPPORTERS SAY:

SB 339 would provide an effective, compassionate-use option for people with intractable epilepsy, including children, for whom other treatments have not controlled their seizures. These people are at high risk of death or brain damage due to repeated seizure and do not have time to wait for the Food and Drug Administration (FDA) trial process to complete before having the option to try this drug. The drug has undergone some testing for side effects, even if it has not gone through FDA trials. Its "orphan drug" designation does not guarantee that a trial will move quickly, and the FDA may not ever approve botanical forms of low-THC cannabis that

could treat epilepsy in children.

SB 339 is not a recreational marijuana or broad medical marijuana bill; it is narrowly drafted to give people with epilepsy another tool where others have failed. It would apply only to low-THC cannabis, a form that has a low propensity for abuse and no street value on the black market. The bill limits THC in the treatment to 0.5 percent, which is not enough to produce a euphoric effect. Low-THC cannabis must contain at least 10 percent cannabidiol, a substance in cannabis that has therapeutic properties but does not lead to intoxication. The low-THC cannabis for medical use could not be smoked, and the bill would establish a compassionate-use registry, both of which would lower the potential for abuse.

FDA-approved drugs that parents can obtain to stop children's seizures are stronger than low-THC cannabis, with a higher street value. No FDA-approved drugs are approved for Dravet Syndrome, a dangerous form of epilepsy that manifests in very young children. The bill would provide these children with another option.

Only patients who were Texas residents with intractable epilepsy could receive a prescription for low-THC cannabis. A physician would weigh the risks and benefits under strong regulations, and only those who were board-certified in epilepsy or certain disciplines within neurology could prescribe the treatment. A second physician would have to concur with the decision. Prescribing physicians would have to register with the Department of Public Safety (DPS) and would have to detail the treatment plan and dosage for their patients. Dispensers also would have to be registered and licensed through DPS, which could seize the treatment and drug paraphernalia if a dispensing organization's license were revoked.

Other states have legalized this treatment, and Texas families who wish to legally obtain low-THC cannabis to treat their child's epilepsy sometimes must move to another state.

FDA-approved treatments can have worse side effects than low-THC cannabis, such as rashes, respiratory depression, risk of fatal liver failure,

kidney stones, or pneumonia. Patients who have used low-THC cannabis have not reported these side effects. Sleepiness is the most common side effect for this treatment, even in combination with other drugs.

In general, anti-epileptic drugs, including those approved by the FDA, work by affecting the brain. Concerns about the effect of low-THC cannabis on a child's brain also could be applied to FDA-approved anti-epileptic drugs because many of them were not clinically tested for use with children, but for adults. Many FDA-approved anti-epileptic drugs also have value on the black market. This alone is not a reason to reject an effective treatment.

OPPONENTS SAY:

SB 339 runs the risk of causing harm by allowing patients to use a treatment that has not yet been approved by the Food and Drug Administration (FDA). Children's brains are still developing and could be harmed by using a treatment that has not been proven to be safe and effective.

Patients wishing to use low-THC cannabis should wait for this treatment to be fully tested because the side effects for this treatment are relatively unknown. Low-THC cannabis has been designated as an "orphan drug" by the FDA, which means that the trial process is likely to move quickly for this treatment.

SB 339 also could create the opportunity for other children, such as those in the same household, who were not prescribed the treatment to use low-THC cannabis if they were not properly supervised. While the treatment would be low-THC, it would not be free of THC and could still be sold on the black market.

SB 339 also would not provide adequate regulation for the sale of low-THC cannabis. The bill could lead to children being accidentally given a high-THC product if dispensers were not properly regulated.

The fact that other states have enacted similar legislation is not a reason for Texas to move forward and do the same.

NOTES:

The House companion bill, CSHB 892 by Klick, was placed for second-reading consideration on the May 13 General State Calendar but was not considered.