BILL ANALYSIS

C.S.H.B. 805
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

It has been suggested that the process to be granted access by the U.S. Food and Drug Administration (FDA) to unapproved drugs that are in the clinical trial phase is arduous and lengthy and comes at a phase of illness when most terminally and chronically ill patients do not have the time to wait. C.S.H.B. 805 seeks to set out the Medical Freedom Act to allow patients with severe chronic diseases to safely and more quickly access experimental treatments that are not yet approved by the FDA.

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 in SECTION 2 of this bill.

ANALYSIS

C.S.H.B. 805 amends the Health and Safety Code to make certain patients with a severe chronic disease as defined by the bill eligible to access and use an investigational drug, biological product, or device as defined by the bill. The bill specifies that the term "investigational drug, biological product, or device" does not include low-THC cannabis or a product containing marihuana regardless of whether the cannabis or product has successfully completed phase one of a clinical trial. The bill sets out eligibility requirements for such access and use and requires the commissioner of state health services to designate the medical conditions that are considered severe chronic diseases for such purposes.

C.S.H.B. 805 requires an eligible patient to sign a written informed consent before receiving an investigational drug, biological product, or device and authorizes a parent, guardian, or conservator of a patient who is a minor or who lacks the mental capacity to provide informed consent to provide informed consent on the patient's behalf. The bill authorizes the commissioner to prescribe a form for the required informed consent.

C.S.H.B. 805 expressly does not create a private or state cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using that item for any harm to the patient resulting from that item. The bill prohibits an official, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device unless the item is considered adulterated or misbranded under the Texas Food, Drug, and Cosmetic Act. The bill prohibits a governmental entity from considering the item to be adulterated or misbranded solely on the basis that the FDA has not approved it. The bill

expressly does not affect the coverage for routine patient care costs of enrollees in certain clinical trials.

C.S.H.B. 805 prohibits the Texas Medical Board from revoking, failing to renew, suspending, or taking any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, provided that the recommendations meet the medical standard of care and the requirements of the bill's provisions.

C.S.H.B. 805 sets out certain legislative findings and intent. The bill requires the executive commissioner of the Health and Human Services Commission (HHSC) to adopt rules necessary to administer the bill's provisions and authorizes the executive commissioner to adopt initial rules in the manner provided by law for emergency rules.

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. 805 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 includes a requirement for the executive commissioner of HHSC to adopt rules necessary to administer the bill's provisions. The substitute replaces an authorization for the executive commissioner by rule to adopt an informed consent form with an authorization for the commissioner to prescribe such a form.

The substitute changes the definition of "severe chronic disease" from a condition, injury, or illness that lasts for at least one year, requires ongoing medical attention, and entails significant functional impairment or severe pain that limits a person's activities of daily life to a condition, injury, or illness that may be treated, may not be cured or eliminated, and entails significant functional impairment or severe pain. The substitute changes from the executive commissioner to the commissioner of state health services the person required to designate the medical conditions that are considered severe chronic diseases.

The substitute includes a provision specifying that the term "investigational drug, biological product, or device" does not include low-THC cannabis or a product containing marihuana regardless of clinical trial status.

The substitute includes the following:

- an exception to the prohibition against an official, employee, or agent of the state blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device for a drug, product, or device considered adulterated or misbranded; and
- a prohibition against a governmental entity considering a drug, biological product, or device to be adulterated or misbranded solely on the basis that the FDA has not approved the drug, product, or device.