HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES

CHAPTER 490. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 490.001. DEFINITIONS. In this chapter:

(1) "Commissioner" means the commissioner of state health services.

(2) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(3) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but the United States Food and Drug Administration or its international equivalent has not yet approved for general use and that remains under investigation in the clinical trial. The term does not include low-THC cannabis, as defined by Section 169.001, Occupations Code, or a product containing marihuana, as defined by Section 481.002, regardless of whether the cannabis or product successfully completed phase one of a clinical trial.

(4) "Severe chronic disease" means a condition, injury, or illness that:

(A) may be treated;

(B) may not be cured or eliminated; and

(C) entails significant functional impairment or severe pain.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES. The commissioner shall designate the medical conditions considered to be severe chronic diseases under this chapter.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

Sec. 490.003. RULES. The executive commissioner shall adopt rules necessary to administer this chapter.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH SEVERE CHRONIC DISEASES

Sec. 490.051. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational drug, biological product, or device under this chapter if:

(1) the patient has a severe chronic disease the commissioner designates under Section 490.002 that the patient's treating physician confirms in writing;

(2) the use of the investigational drug, biological product, or device is consistent with this chapter and rules adopted under this chapter; and

(3) the patient's physician:

(A) in consultation with the patient, considers all other treatment options the United States Food and Drug Administration has currently approved and determines those treatment options are unavailable or unlikely to provide relief for the significant impairment or severe pain associated with the patient's severe chronic disease; and

(B) recommends or prescribes in writing the patient's use of a specific class of investigational drug, biological product, or device.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

Sec. 490.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent. 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.

(b) The commissioner may prescribe a form for the informed consent required under this section.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

Sec. 490.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with this chapter if the patient provides to the manufacturer the informed consent required under Section 490.052.

(b) This chapter does not require a manufacturer to make available an investigational drug, biological product, or device to an eligible patient.

(c) If a manufacturer makes available an investigational drug, biological product, or device to an eligible patient under this subchapter, the manufacturer must provide the investigational drug, biological product, or device to the eligible patient without receiving compensation.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

Sec. 490.054. CAUSE OF ACTION NOT CREATED. This chapter 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 the investigational drug, biological product, or device for any harm to the patient resulting from the investigational drug, biological product, or device.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

Sec. 490.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official, employee, or agent of this state may not block or attempt to block an eligible patient's access to an investigational drug, biological

product, or device under this chapter unless the drug, biological product, or device is considered adulterated or misbranded under Chapter 431. For purposes of this section, a governmental entity may not consider the drug, biological product, or device to be adulterated or misbranded based solely on the United States Food and Drug Administration not yet finally approving the drug, biological product, or device.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 490.101. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES. This chapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.

SUBCHAPTER D. PHYSICIANS

Sec. 490.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, Occupations Code, 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 requirements of this chapter and rules adopted under this chapter.

Added by Acts 2023, 88th Leg., R.S., Ch. 1082 (S.B. 773), Sec. 2, eff. June 18, 2023.