By: Hughes S.B. No. 670

A BILL TO BE ENTITLED

AN ACT

relating to patient authorization to access certain investigational sun protection products.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. (a) The legislature finds that:

(1) the process for the approval of investigational sun protection products in the United States takes many years;

(2) some patients do not have the luxury of waiting until an investigational sun protection product receives final approval from the United States Food and Drug Administration;

(3) the standards of the United States Food and Drug Administration for the use of investigational sun protection products may deny patients the benefits of potentially life-saving products;

(4) patients have a fundamental right to attempt to preserve their health and lives by accessing available investigational sun protection products;

(5) the use of available investigational sun protection products is a decision the patient in consultation with the patient's physician should make to preserve the patient's health or life and is not a decision the government should make; and

(6) the decision to use an investigational sun protection product should be made with full awareness of the potential risks, benefits, and consequences to the patient.

(b) It is the intent of the legislature to allow patients the option of using investigational sun protection products.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 491 to read as follows:

CHAPTER 491. PATIENT ACCESS TO INVESTIGATIONAL SUN PROTECTION PRODUCTS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 491.001. DEFINITION. In this chapter, "investigational sun protection product" means a sun protection product containing an ingredient that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in the clinical trial.

SUBCHAPTER B. ELIGIBLE PATIENT ACCESS TO INVESTIGATIONAL SUN PROTECTION PRODUCTS

Sec. 491.051. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational sun protection product if the patient's physician:

(1) in consultation with the patient, has considered all other sun protection products currently approved by the United States Food and Drug Administration and determined those products are less effective in comparison to an investigational sun protection product; and

(2) recommends or prescribes in writing an investigational sun protection product for the patient.

Sec. 491.052. INFORMED CONSENT. (a) Before recommending or prescribing an investigational sun protection product, a

physician must require an eligible patient to sign a written informed consent form.

(b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian may provide informed consent on the patient's behalf.

(c) The Texas Medical Board by rule may adopt a form for the informed consent required under this section.

Sec. 491.053. PROVISION OF INVESTIGATIONAL SUN PROTECTION PRODUCT. (a) A manufacturer of an investigational sun protection product may make available in accordance with this chapter and any rules adopted under this chapter the manufacturer's product to eligible patients who provide to the manufacturer the informed consent required under Section 491.052.

(b) This chapter does not require a manufacturer to make available an investigational sun protection product to an eligible patient.

(c) A manufacturer may:

(1) provide an investigational sun protection product to an eligible patient without receiving compensation; or

(2) require an eligible patient to pay the manufacturer's costs of, or costs associated with, the manufacture of the product.

Sec. 491.054. NO CAUSE OF ACTION CREATED. This chapter does not create a private or state cause of action against a manufacturer of an investigational sun protection product or against any other person or entity involved in the care of an eligible patient using the product for any harm to the eligible patient resulting from the

product.

Sec. 491.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL SUN PROTECTION PRODUCTS. An official, employee, or agent of this state may not block or attempt to block an eligible patient's access to an investigational sun protection product under this chapter.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 491.101. 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.

SUBCHAPTER D. PHYSICIANS

Sec. 491.151. PROHIBITED ACTION AGAINST PHYSICIAN'S LICENSE. 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 recommendation to or prescription for an eligible patient regarding access to an investigational sun protection product, provided the recommendation or prescription for the patient meets the medical standard of care and the requirements of this chapter.

SECTION 3. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2025.